ECONOMIC EVALUATION OF THE NPS MEDICINEWISE PROGRAM

PROTON PUMP INHIBITORS: TOO MUCH OF A GOOD THING? (2015)

Cost-Benefit Analysis Report
August 2018

Independent, not-for-profit and evidence based, NPS MedicineWise enables better decisions about medicines and medical tests. NPS MedicineWise receives funding from the Australian Government Department of Health.

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EXECUTIVE SUMMARY

This cost-benefit analysis assessed the value of the NPS MedicineWise 2015 Proton Pump Inhibitor (PPI) program from the perspective of the payer, the Australian Government Department of Health (DoH). In April 2015, NPS MedicineWise launched the PPI program which was active for 12 months. The aim of the program was to provide the opportunity for GPs to reflect on their current practice and prescribing patterns with the goal of reducing GPs inappropriate prescribing of PPIs, particularly high-strength PPIs. The PPI program, a non-visiting program, included: a national case study; a clinical audit; PBS feedback; MedicineWise News; NPS Direct; a Choosing Wisely recommendation; online videos; knowledge hubs; and a symptomatic management pad.

Proton Pump Inhibitors (PPIs) are mainly used to treat symptoms of gastro-oesophageal reflux disease (GORD) and peptic ulcer disease. Despite the indication for long term PPI use for ongoing problems with GORD and a limited number of other indications, there is evidence that PPIs are inappropriately prescribed and overused in both primary care and hospital settings. The majority of PPI use is in older people with higher strength products prescribed despite guidelines recommending that standard daily doses of higher strength PPIs be used only for initial treatment for a short time for GORD, functional dyspepsia, peptic ulcer disease, Barrett's oesophagus and oesophagitis. Recommended that treatment with PPIs can usually be stepped down after an initial 4-8 week course. Long-term use of PPIs accounts for a large proportion of patients receiving treatment. It is estimated that up to a third of patients receiving treatment with PPIs may be able to cease treatment after the initial course. The overuse of PPIs presents an important quality use of medicines issue, and may increase risks of adverse effects and incur unnecessary costs for both taxpayers and individuals.

This cost-benefit analysis of the PPIs program identifies in monetary terms, the costs and benefits of the program. The financial impact of the PPI program was calculated in terms of reducing costs to the Pharmaceutical Benefits Scheme (PBS). A time series analysis using PBS data was conducted to estimate the changes in volume of dispensed high strength PPIs. The PBS data were obtained from the Australian Government Department of Human Services (DHS) for the period 1 January 2006 to 30 June 2017. Program costs incurred by NPS MedicineWise to conduct the interventions were used to calculate the cost of the program.

The PPI program produced a positive cost-benefit due to the decrease in dispensed prescriptions for high-strength PPIs. The intervention resulted in a total decrease of 843,748 prescriptions of high strength PPIs over the period between April 2015 and June 2017. With the average cost of a PPI prescription valued at \$15.33, a monetary benefit to the payer of \$11,992,233 was produced. The costs of the program was \$426,251.

Summary of Findings

For every dollar spent on the NPS MedicineWise PPI program to improve appropriate prescribing of high strength PPIs in general practice, \$29 in monetary benefit was gained by the payer, the Australian Government Department of Health due to reduced prescriptions of high-strength PPIs.

INTRODUCTION

Proton Pump Inhibitors

Proton Pump Inhibitors (PPIs) are mainly used to treat symptoms of gastro-oesophageal reflux disease (GORD) and peptic ulcer disease and are one of the most commonly prescribed classes of medicines in Australia.1 At least two PPIs are annually on the top 10 most commonly prescribed medicines subsidised under the Pharmaceutical Benefits Scheme (PBS). In the 2013-14 financial year, over 19 million prescriptions of PPIs were provided. The most commonly prescribed PPI in 2013-14 incurred a cost of over \$200 million to the PBS. 10 Despite the indication for long term PPI use for ongoing problems with GORD and a limited number of other indications^{2,3} there is evidence that PPIs are inappropriately prescribed and overused in both primary care and hospital settings. 4.5.6 In Australia, according to OECD data, PPI usage increased from 44.0 defined daily doses per 1000 population in 2000 to 77.5 in 2015.11 Long-term use of PPIs accounts for a large proportion of patients receiving treatment. The majority of PPI use is in older people with higher strength products prescribed⁷ despite guidelines recommending that standard daily doses of higher strength PPIs should be used only for a short time and as initial treatment of GORD, functional dyspepsia, peptic ulcer disease. Barrett's oesophagus and oesophagitis.^{2,8,9} It is recommended that treatment with PPIs usually be stepped down after an initial 4 to 8 week course. It is estimated that up to a third of patients receiving treatment with PPIs may be able to cease treatment after the initial course. 10 The overuse of PPIs presents an important quality use of medicines issue, and may increase risks of adverse effects and incur unnecessary costs for both taxpayers and individuals.10

Although PPIs have an excellent safety profile there are severe, albeit rare, adverse effects associated with PPIs which have been reported in a number of observational studies such as enteric infections, pneumonia, fractures and acute interstitial nephritis.¹⁰

About the program

NPS MedicineWise launched the 'Proton Pump Inhibitors' program in April 2015 and was active for approximately 12 months, ending in April 2016. The aim of the program was to provide the opportunity for GPs to reflect on their current practice and prescribing patterns for PPIs. The goal of the program was to reduce GPs' inappropriate prescribing of PPIs, particularly high-strength PPIs for patients managed in primary care.

The key messages for the program included:

- Review all existing patients taking PPIs
- Confirm whether the indication for treatment remains and whether the dose of PPI can be reduced or stopped
- Encourage lifestyle modifications and review use of drugs that exacerbate dyspepsia symptoms
- Decrease PPI use to low doses or intermittent, symptom-driven therapy once symptoms are controlled
- Always discuss the expected duration of treatment and have a plan for stepping down or stopping treatment when patients are started on PPIs

There were four GP-focussed objectives developed for the PPI program:

- Increase the proportion of GPs who select patients to benefit from a review of their PPI therapy
- ▷ Increase the proportion of GPs who differentiate the duration of PPI therapy required at high and low doses
- > Increase the proportion of GPs who implement the appropriate step-down PPI therapy

▶ Increase the proportion of GPs who initiative PPIs as a trial and undertake a review at 4-8 weeks

The 2015 PPIs program incorporated a number interventions delivered to GPs including: a national case study; clinical audit; PBS feedback; MedicineWise News; NPS Direct; a Choosing Wisely recommendation; online videos; knowledge hubs; and a symptomatic management pad. GP participation in interventions and expected program outcomes are presented in Figure 1. The PBS Feedback is presented in Appendix 2. This was a non-visiting program.

Figure 1: Expected outcomes of the NPS MedicineWise PPI Program

INPUTS	OUTPUTS	OUTCOME	IMPAC	т
INTERVENTIONS	PROGRAM KEY MESSAGES FOR HEALTH PROFESSIONALS	EXPECTED CHANGES IN GPs' BEHAVIOUR / CLINICAL	OUTCOMES (POPULATION → PERSON)	COSTS
PBS Feedback (n ≈ 24,000 GPs) Case Study (n = 648 GPs) Clinical Audit (n = 1302 GPs)	1. Review all existing patients taking PPIs. 2. Confirm whether the indication for treatment remains and whether the dose of PPI can be reduced or stopped. 3. Encourage lifestyle modifications and review use of drugs that exacerbate dyspepsia symptoms. 4. Decrease PPI use to low doses or intermitten, symptom driven therapy once symptoms are controlled.	PRACTICE	↓ First-line use of high- strength statins	↓ PBS expenditure on high-strength statins
	5. Always discuss the expected duration of treatment			

COST-BENEFIT ANALYSIS

Methods

Cost-benefit analysis was used to compare the costs and effects of the PPIs program, expressed in monetary terms from the perspective of the payer. The payer is the Commonwealth Department of Health which funds the quality use of medicines (QUM) programs implemented by NPS MedicineWise. The measures used in this analysis are:

- ➤ The costs of the resources required to deliver the PPIs program. Program cost data was collected from NPS MedicineWise organisational timesheet data, invoice records and budget data.
- ➤ The benefits of the program expressed as the monetary value of the effects generated by the program. The benefits are restricted to the direct savings associated with the reduction in PBS benefits paid. Time series analysis was used to quantify the impact of the PPIs program on GP prescribing of high-strength PPIs. Based on actual PBS prescribing volumes, statistical models were developed to estimate the volume of PBS prescribing for these medicines. Prescribing volumes were estimated with and without the NPS MedicineWise intervention.

The cost-benefit was calculated from the program net benefit and the benefit-cost ratio. The *net benefit* is calculated as the difference between the benefits and the costs. Values higher than zero indicate that monetary benefits exceed monetary costs, while the *benefit-cost ratio* is calculated as the ratio of benefits to costs. Values higher than one indicate that the benefits exceed the costs.

Provider level dispensing and reimbursement data for PPIs listed on the PBS (Table 1) were obtained from the DHS. The data covered the period from 1 January 2006 to 30 June 2017 and was supplied in aggregate form at the GP level. The PBS data comprises the number of subsidised scripts prescribed, both original and repeats, with a breakdown by general and concessional beneficiary entitlement levels. Repatriation Pharmaceutical Benefits Scheme (RPBS) data were not included.

The PBS data were supplied according to the following specifications:

- Vocationally Registered General Practitioners (VRGP's) and Other Medical Practitioners (OMPs)
- PBS prescribing by scrambled provider number
- ▶ 1 January 2006 to 30 June 2017 time period
- Date of prescribing and date of supply of medicine
- Price and net benefit of scripts by PBS medication item code

Costs and benefits were adjusted to 2017/2018 financial year equivalent value, using Australian CPI values published by the Australian Bureau of Statistics (ABS) and discounted at a rate of 5% per year after the first year.³ The cost-benefit summary is presented in Table 4.

Table 1: High-strength PPIs included in analysis

Class	Active Ingredient	Dose form and strength (mg/dose unless otherwise specified)
	Esomeprazole	40mg tablet (30)
	Lansoprazole	30mg tablet (28)
PPIs	Omeprazole	20mg capsule (30)
	Pantoprazole	40mg tablet (30)
	Rabeprazole	20mg capsule (30)

Results

PBS Utilisation of High-Strength PPIs

The PPIs program was associated with a decrease in dispensing of high-strength PPIs (Esomeprazole, Lansoprazole, Omeprazole, Pantoprazole and Rabeprazole). For the period April 2015 to June 2017, the average estimated reduction in PBS dispensing volume of high-strength PPIs associated with the PPIs program was 843,748 concessional prescriptions. This represents a relative decrease of 4% in the modelled PBS volume. The average cost to the PBS per dispensing was \$15.33 for the period April 2015 to June 2017, giving a gross cost decrease attributable to the program of \$12,560,951.

In Figure 2, the shaded area between the estimated volume with (red trend line) and without (represented by a green trend line) without the PPIs program represents the impact of the program in decreasing the volume of high-strength PPIs dispensed.

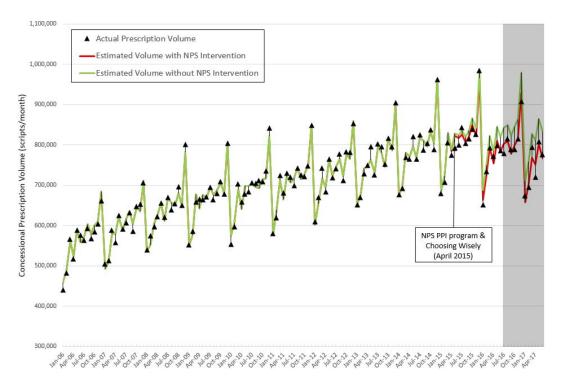


Figure 2: Time series analysis of PBS dispensing of high-strength PPIs

Program Costs

Invoiced costs for the program were sourced from data obtained directly from NPS MedicineWise's internal finance department. NPS MedicineWise uses a 24% increase, applied to total staff costs per financial year, in order to account for the cost of infrastructure and support services used in program development and delivery.

All costs were adjusted to the 2017/2018 financial year equivalent value using Australian CPI values published by the ABS. 12 Program costs and savings to the PBS after the first year (2014/15) were discounted at a rate of 5% per year.

Table 2: PBS expenditure change associated with NPS MedicineWise PPI Program

Type PPI	2014/15	2015/16	2016/17	Total (Unadjusted)	Total (adjusted to 2017 equivalent)	Total (adjusted & discounted)
High Strength PPIs	♥ \$220,246	4 ,403,385	◆ \$7,937,320	◆ \$12,560,951	◆ \$12,820,935	◆ \$12,418,484

Table 3: NPS MedicineWise PPI Program costs

	Unadjusted	Adjusted to 2017 equivalent	Adjusted and Discounted 5%	2014/15	2015/16	2016/17	Source
Invoiced	\$90,937	\$95,087	\$95,087	\$90,937	\$0	\$0	Invoices from PPIs program
Staff costs	\$255,520	\$267,071	\$267,068	\$247,909	\$7,546	\$64	Timesheet and
Infrastructure/support services	\$61,325	\$64,097	\$64,096	\$59,498	\$1,811	\$15	human resources data for PPIs program
Total Program Costs	\$407,781	\$384,979	\$362,155	\$398,345	\$9,357	\$79	

Table 4: Cost benefit summary of the PPI Program

	Unadjusted	Adjusted to 2016 equivalent	Discounted and adjusted
Total program costs	\$407,781	\$426,255	\$426,251
Total change in PBS cost	\$12,560,951	\$12,820,935	\$12,418,484
Total benefit of program	\$12,560,951	\$12,394,680	\$11,992,233
Benefit to cost ratio	\$31	\$30	\$29

The total benefit of the program is the sum of the change in PBS costs minus the costs of the NPS MedicineWise program: \$12,418,484 - \$426,251 = **\$11,992,233**. This represents a monetary gain as a result of the program. The benefit to cost ratio is calculated by dividing the estimated cost of changing prescribing patterns by the cost of the NPS MedicineWise program.

Benefit to cost ratio: 11,992,233/426,251= 29

Values higher than one indicate that the benefits exceed the costs. The value of 29 indicates that for every dollar spent on the program, \$29 in monetary benefit was gained.

DISCUSSION

Changes were observed in PPI dispensing associated with the NPS MedicineWise PPI (2015) program. This change aligned with the anticipated outcomes of the program. Subsequent to the delivery of the program, dispensing of PPIs decreased by 7.2% from the predicted trend had the intervention not taken place, which resulted in savings of \$12,418,484 after accounting for discounting and adjustment. The change in PPI dispensing could have been further influenced by the release of a Choosing Wisely recommendation.

The cost of development and delivery of the program was \$426,251 after accounting for discounting and adjustment. The cost-benefit analysis returned a total net monetary benefit attributable to the program of \$11,992,233 from the perspective of the payer, the Australian Government Department of Health. The benefit to cost ratio was 29 indicating that the financial benefits exceed the costs of the program.

Time series analysis was used to quantify the impact of the 2015 PPI program by investigating whether there was a statistically significant change in trend over a defined period of time that could be attributed to the program. The strengths of the cost-benefit analysis include the quality of the data used and the suitability of the time-series method to accurately estimate the attributable effect of the 2015 PPI program. Program cost data was sourced directly from NPS MedicineWise organisational records and invoiced records which captured internal and external costs of the program from inception until completion.

A strength of this analysis was that the PBS data used included all dispensed prescriptions and claims reimbursed by the PBS for the Australian population apart from veterans. The analysis of the change in low strength PPIs was not included in this report as no changes were detected over the time period.

The cost-benefit analysis presented by this report provides evidence that the NPS MedicineWise PPI program was an efficient use of public resources. The intervention resulted in a total decrease of 843,748 prescriptions over the period between April 2015 and June 2017. With the average cost of a PPI prescription valued at \$15.33, a monetary benefit to the payer of \$11,992,233 was produced. For every dollar spent on the NPS MedicineWise PPI program to improve appropriate prescribing of high strength PPIs in general practice, \$29 in monetary benefit was gained by the payer, the Australian Government Department of Health due to reduced prescriptions of high-strength PPIs.

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APPENDIX 1: COSTS OF PROTON PUMP INHIBITORS (PBS)

Drug	PBS item numbers	Dispensed Price	
Esomeprazole	8601Q	\$22.05	
Lansoprazole	2240X	\$16.96	
	2241Y	\$16.96	
	9477T	\$16.96	
	9478W	\$16.96	
Omeprazole	1326T	\$15.76	
	1327W	\$15.76	
	8331L	\$15.76	
	8333N	\$15.76	
	9109K	\$15.76	
	9110L	\$15.76	
Pantoprazole	8007K	\$13.88	
	8008L	\$13.88	
	9423Y	\$32.45	
	9424B	\$32.45	
Rabeprazole	8508T	\$14.37	
	8509W	\$14.37	

APPENDIX 2. PBS FEEDBACK



TOO MUCH OF A GOOD THING PPI PRESCRIBING

Practice Review: PBS data March 2015



► 000001 000 0Hs Dr Sam Sample 123 Sample Street SAMPLETOWN ABC 1234 These data have been provided for your personal reflection only and are not used for any regulatory purposes.

16 March 2015

Dear Dr Sample,

NPS MedicineWise supports clinicians in professional development and continuing quality improvement with a focus on quality use of medicines and medical tests. As part of this we provide you with selected data on medicines and medical tests. The focus of the enclosed data is the dispensing of your prescriptions for proton pump inhibitors (PPIs). We highlight that this information is confidential; NPS MedicineWise does not have access to your Individual prescribing data. These data have been provided for your personal reflection only and are not used for any regulatory purposes.

PPIs: too much of a good thing?

In Australia, PPIs are one of the most widely prescribed classes of medicines. Although they are effective and generally well tolerated, long-term daily use is often not necessary. PPI treatment for most common conditions (eg, gastro-oesophageal reflux disease [GORD]) can often be stepped down successfully after an initial 4-8 week course. Stepping down can include reducing the PPI dose, switching to symptom-driven therapy or stopping treatment. 4-4

Reflect on your prescribing

The enclosed PBS data provide you with an opportunity to reflect on your practice and your prescribing pattern for PPIs, and to compare this with the median prescribing of GPs in your RRMA."

Learn more

For more information about prescribing PPIs and managing GORD, see the latest Medicinewise News on our website for health professionals and consumers at nps.org.au/medicinewise-news

Look out for NPS MedicineWise CPD activities and tools to help improve your practice:

- · Case study focusing on PPI treatment in uncomplicated GORD
- · Clinical e-Audit helping you rationalise your PPI prescribing
- Symptomatic management pad an easy way to help patients self-manage GORD symptoms.

These will become available throughout 2015. Check our website nps.org.au regularly or sign up to our GP Update e-newsletter at nps.org.au/gpupdate to be alerted when CPD activities become available.

Yours sincerely,

Peter Turner Chair

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medicines and medical tests. We receive funding from the Australian Government Department of Health

National Prescribing Service Limited ABN 61 082 034 393



Your confidential prescribing data

NPS MedicineWise provide these data for your reflection only. The data are from the Department of Human Services and include all PBS prescriptions for proton pump inhibitors (PPIs) that you prescribed that were dispensed. The indication for prescribing (ie, whether for GORD, peptic ulcer disease or another condition) cannot be determined from PBS data, so you will need to think about your patients and their indications for PPI therapy.

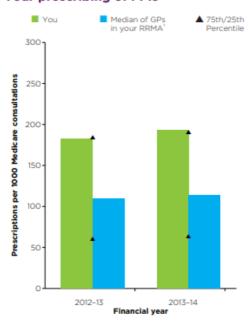
Proton pump inhibitor (PPI) therapy

PPIs are one of the most widely used medicines in Australia. During the financial year 2013-14, PPIs were one of the most frequently dispensed drugs in Australia - dispensed over 17 million times - and contributed around \$350 million to the PBS expenditure.

Although PPIs are highly effective at reducing symptoms caused by gastric acid and are generally well tolerated, long-term daily use is often not necessary. PPIs should be used at the lowest effective dose for the shortest period. In GORD, oesophagitis and peptic ulcer disease, 4-8 weeks of PPI treatment will often heal the gastrointestinal tract.⁵ In these conditions, longer term PPI treatment will be determined by risk of recurrence of complications or ongoing symptoms.

- When do you review the need for ongoing PPI treatment?
- Do you review the need for other medicines that may contribute to upper gastrointestinal symptoms?
- Do you step down to the lowest dose and frequency of PPI that is effective, when appropriate?

Your prescribing of PPIs



Points for reflection

- Confirm the need for ongoing PPI treatment. After an initial 4-8 week course of PPIs, around 30% of patients with uncomplicated GORD can expect to be symptom free for a prolonged period after discontinuing PPI therapy.
- Assess for modifiable factors contributing to symptoms, including other medicines (eg, NSAIDs) and lifestyle factors such as obesity and smoking.2
- PPIs can potentially cause adverse effects such as headache, nausea, vomiting, diarrhoea, abdominal pain and, rarely, acute interstitial nephritis.6

Number and cost of PPI prescriptions dispensed

	You				All GPs	
Year	Number of prescriptions	Total cost (\$)	Percentage of your total PBS cost	Number of prescriptions	Total cost (\$)	Percentage of total PBS cost
2013-14	944	15,349	6%	17,261,340	290,693,942	6%

Practice Review

PPI prescribing: too much of a good thing

PPI use by strength of product

	Percentage of PPI prescriptions					
	Y	ou	Median of GPs in your RRMA			
	2012-13	2013-14	2012-13	2013-14		
Lower strength products esomeprazole 10 mg, 20 mg [#] lansoprazole 15 mg omeprazole 10 mg pantoprazole 20 mg rabeprazole 10 mg	28%	23%	28%	29%		
Higher strength products esomeprazole 40 mg lansoprazole 30 mg omeprazole 20 mg pantoprazole 40 mg rabeprazole 20 mg	72%	77%	71%	71%		

[#] Esomeprazole 20 mg strength, taken once daily is considered both standard and low dose. Note: Due to rounding, percentages of PPI prescriptions may not total 100%.

Points for reflection

- A standard PPI dosage is 1 tablet/capsule daily of a higher strength product, with the exception of esomeprazole^{#,6,7}
- ▷ In common uncomplicated conditions, (eg, GORD) start treatment with a 4-8 week course of standard PPI dosage, after excluding alarm symptoms (eg, unexplained weight loss, haematemesis, melaena, dysphagia, odynophagia).^{2,4,6}
- ▷ If symptoms are well controlled, step down treatment to a low dose (eg, lower strength PPI), switch to symptom-driven therapy or stop PPI treatment. 4,6

Number of patients who have been using long-term PPI therapy

	You				Med	lian of GPs	in your RR	MA [*]
	201	2-13	201	3-14	201	2-13	201	3-14
Number of patients and percentage of all prescribed a PPI who had more than 6 PPI prescriptions dispensed	53	32%	61	38%	29	28%	30	28%

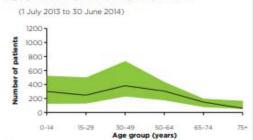
Points for reflection

- Discuss expected duration and goals of treatment with the patient when starting PPI therapy.³
- Identify patients on long-term PPI therapy and review the need for continuing use.
- Support patients when stepping down PPI treatment, with clear instructions on how to self-manage symptoms with PPIs or other medicines.
- Offer lifestyle advice that may reduce upper gastrointestinal symptoms.

Practice profile

Data are presented as prescribing rates (per 1000 Medicare consultations) to adjust for volume of service. The age profile of patients in your practice is provided to help you interpret your prescribing data.

Age profile of patients in your practice



The black line represents the age profile of patients in your practice. 25% to 75% of GPs in your RRMA <code>'fall</code> within the shaded area. Your RRMA peer group is f t

Medicare patients and concession card holders in your practice

(1 April 2014 to 30 June 2014)

Patients	You	Median GPs in your RRMA
Total Medicare	576	637
Concession card holders Includes those reaching Safety Net	185	144

Data from a 3 month period that best represents patient mix have been provided.

Confidentiality

NPS MedicineWise has a contract with the Department of Human Services to provide your PBS prescribing data directly to you. NPS MedicineWise does not have access to these data. The data contained in this report are not used for any regulatory purposes.

Disclaimer

This information is derived from a critical analysis of a wide range of authoritative evidence. Reasonable care is taken to provide accurate information at the time of creation. This information is not intended as a substitute for medical advice and should not be exclusively relied on to manage or diagnose a medical condition. NPS MedicineWise disclaims all liability (including for negligence) for any loss, damage or injury resulting from reliance on or use of this information.

Discrepancies may occur between the data provided and your own practice. This may be due to either inaccurate recording of your prescriber number in the pharmacy or your prescription pad having been used by another doctor.

If you consider your individual data to be incorrect, have other data queries or general feedback please contact NPS MedicineWise on 02 8217 8700 or by email at info@nps.org.au

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Notes

- || Data shown are an aggregate for all your provider locations.
- † The comparator group "other GPs in your RRMA" includes all general practitioners currently located in a similar geographical region ie, 1, capital cities, 2, other metropolitan centres, 3, large rural centres.
 - 4. small rural centres, 5. other rural centres, 6. remote centres and 7. other remote centres.

Your RRMA peer group is 1.

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Practice Review

PPI prescribing: too much of a good thing