

# PROGRAM RULES Take Home Naloxone

August 2023





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**CONTACT THE SUPPORT CENTRE:** 1800 951 285 | support@ppaonline.com.au

#### **1** INTRODUCTION

This document outlines the Program Rules governing the Take Home Naloxone (THN) Program for Approved Providers. This document must be read in conjunction with the Pharmacy Programs Administrator (PPA) General Terms and Conditions (General Terms).

Definitions in the General Terms apply in these Program Rules.

#### 2 BACKGROUND

Naloxone is a medicine that rapidly reverses the effects of an opioid overdose. It can be administered by injection or through a nasal spray. Under the THN Program, naloxone is available free, in all Australian States and Territories, to people who are at risk of or who may witness an opioid overdose or adverse reaction. A prescription is not required for supply.

Following the evaluation of the Take Home Naloxone Pilot Program, which ran from 1 December 2019 to 30 June 2022, the 2022-23 Federal Budget included \$19.6 million (and \$4.9 million per year ongoing) for a National, THN Program commencing from 1 July 2022.

More information about the Take Home Naloxone Pilot can be found here.

#### **3 PARTICIPATION**

Under the THN Program, each State or Territory will identify where naloxone will be made available.

Participating sites providing naloxone to individuals are defined as either an <u>Approved Provider</u> or an <u>Authorised Alternative Supplier</u>.

Approved Providers include community pharmacies, hospital-based pharmacies and approved medical practitioners. Approved providers will supply naloxone and be reimbursed by the Pharmacy Programs Administrator (PPA).

Organisations such as alcohol and other drug treatment services, injecting centres, and homelessness/outreach services in certain states can also supply naloxone by first becoming an Authorised Alternative Supplier (AAS). Information about registering to become an AAS can be found by contacting relevant State or Territory health departments. An AAS can supply naloxone to an individual but does not receive reimbursement from the PPA.

## **3.1** Approved Providers: Community (s90) pharmacies, hospital (s94) pharmacies and approved (s92) medical practitioners

To be eligible to participate in the THN Program, and supply naloxone, Approved Providers must:

- Be approved under sections 90, 92 or 94 of the National Health Act 1953
- Register for the THN Program via the PPA Portal
- Confirm that they are registered for GST
- Agree that the pharmacy/practice trading name and location may be listed on the Department of Health and Aged Care's website and/or provided to participating State/Territory health departments for communications relating to the Program



• Agree to provide services in accordance with these THN Program Rules, including the collection of required **supply claim** data.

Pharmacies and approved medical practitioners are required to source naloxone through their usual supply channel (e.g. pharmaceutical wholesaler). Once naloxone has been supplied free of charge to an individual under the THN Program, a claim for payment can be made via the PPA Portal.

Claiming processes for naloxone dispensed on PBS or private script do not change and cannot be claimed for under the THN Program.

#### 3.2 Authorised Alternative Suppliers

To be eligible to participate in the THN Program, and supply naloxone, an Approved Alternative Supplier (AAS) must:

- Be approved by the relevant State/Territory authority in the relevant jurisdiction (most commonly the health department) to provide naloxone under the THN Program
- Agree to provide services in accordance with these THN Program Rules, including the collection of required **supply claim** data.

Some AASs will also be required to register for the THN Program via the PPA <u>Portal</u> and provide supply claims data directly to the PPA. Please contact your State/Territory health department for more information about requirements to use the PPA Portal.

AASs are required to source naloxone through a variety of mechanisms, depending on their location and should discuss these arrangements with their relevant health authority. Information on who to contact can be found on the <u>Department of Nealth and Aged Care website</u>.

### As at 1 November 2022, AASs in all States and Territories can participate in the THN Program, if their State or **Territo**ry health department has provided approval to do so.

Further information about registering to become an AAS can be found by contacting relevant State or Territory health departments.

#### 3.3 Wholesalers

A wholesaler may provide naloxone to an AAS for distribution to individuals.

To be eligible to participate in the THN Program, and receive payments for naloxone supplied, the wholesaler must:

- Have an arrangement in place with the Commonwealth Government and/or the relevant State/Territory Government to supply naloxone to AASs under the THN Program.
- Register for the THN Program via the PPA Portal
- Confirm that it is registered for GST



- Agree to provide services in accordance with these THN Program Rules, including the collection of required bulk supply data.
  - Note: where costs incurred are associated with distribution from a wholesaler the arrangement and payment of these costs are the responsibility of the relevant State or Territory entering into the arrangement.

#### **3.4 Western Australia Mental Health Commission (WA MHC)**

The WA MHC has an agreement with the Commonwealth Government to supply naloxone to Western Australia AASs under the THN Program and has agreed to provide services in accordance with these THN Program Rules, including the collection of required bulk supply data.

#### 3.5 Individuals receiving naloxone

Any person across Australia is able to access free naloxone, without prescription, under the THN Program.

Specifically, the THN Program aims to make naloxone free and easily available for:

- People who are at risk of an opioid overdose, or adverse reaction, which includes illicit drug users and people who use prescription opioid medications
- Carers, friends and family.

Please note that pharmacists are required to have a conversation with individuals before supplying naloxone and individuals need to agree to be provided with naloxone and understand its purpose and use. Pharmacists also must discuss with individuals whether they consent to provide additional data and collect this, wherever possible.

#### **4 DATA SUBMISSION**

All sites participating in the THN Program are required to submit data, in most instances to the PPA. The data collected is used to:

- Enable the PPA to make payment (where applicable)
- Allow the Commonwealth Government and the relevant State or Territory health department to monitor the supply of naloxone under the THN Program.

Data collected relates to supplies of both naloxone to individuals (known as individual supply claims), as well as the supply of bulk quantities of naloxone to AASs (known as bulk supply claims).

The data your organisation must collect depends on the type of supply (individual or bulk). The requirements for the submission of eligible claims are shown at:

- Appendix A Individual supply claims, relevant for:
  - Community (s90) pharmacies
  - Public and Private Hospital (s94) pharmacies
  - Approved medical practitioners (s92)
  - AASs.
- Appendix B Bulk supply claims, relevant for:
  - Wholesalers and WA MHC
  - Some (s94) hospital pharmacies.



#### **5 PORTAL REGISTRATION**

To become an Approved Provider under the THN Program, pharmacies and approved medical practitioners must first register via the PPA <u>Portal</u>.

Registration will not be complete until the Provider receives email notification from the PPA confirming that registration has been successful.

After approval by the relevant States or Territories, some AASs may also be required to register via the PPA Portal to submit data.

#### **6 FUNDING AVAILABILITY**

The 2022-23 Federal Budget included \$19.6 million (and \$4.9 million per year ongoing) for a National Take Home Naloxone Program, commencing from 1 July 2022,

#### 7 FEES

The following tables contain the fees (including dispensing fee, where applicable) that are payable by the PPA to each applicable Approved Provider for eligible claims made in relation to the supply of naloxone, under the THN Program from 1 July 2022. GST is added to all supplies.

The fees payable for supplies provided between 1 July 2022 and 31 March 2023 can be found in <u>Appendix C</u> of this document.

The fees payable for supplies provided under the Take Home Naloxone Pilot, which ran between 1 December 2019 and 30 June 2022 can be found <u>here</u>,

Alternative Approved Suppliers do not receive fees for supplying naloxone to an individual.

Please note Service Providers can only supply NALOXONE SXP on or after 1 August 2023.

#### Table 7-1: Naloxone supply fees: Community (S90) Pharmacies

Individual Supply (ex GST)	Product
\$49.93	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
<b>\$36.96 Prenoxad</b> (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)	
<b>\$35.10 Naloxone Juno</b> (naloxone hydrochloride 400 microgram/mL injection, 5 ampoules)	
\$35.10	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)
\$35.10	<b>NALOXONE SXP</b> (naloxone hydrochloride 400 microgram/mL injection, $5 \times 1 \text{ mL}$ ampoules)

Individual Supply (ex GST)	Bulk Supply (ex GST)	Product	
\$36.94	\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)	
\$23.97	\$22.29	<b>Prenoxad</b> (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)	
\$22.11	\$20.56	<b>Naloxone Juno</b> (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)	
\$22.11	\$20.56	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)	
\$22.11	\$20.56	<b>NALOXONE SXP</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)	

#### Table 7-2: Naloxone supply fees: Public Hospital (S94) Pharmacies

#### Table 7-3: Naloxone supply fees: Private Hospital (S94) Pharmacies

Individual Supply (ex GST)	Bulk Supply (ex GST)	Product	
\$45.83	\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)	
\$32.68	\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)	
\$30.79	\$20.56	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)	
\$30.79	\$20.56	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)	
\$30.79	\$20.56	<b>NALOXONE SXP</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)	

#### Table 7-4: Naloxone supply fees: Approved Medical Practitioners (S92)

Individual Supply (ex GST)	Product
<b>\$49.93</b> Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)	
\$36.96	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$35.10	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)



\$35.10	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)
\$35.10	<b>NALOXONE SXP</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

#### Table 7-5: Naloxone supply fees: WA MHC and Wholesalers

Bulk Supply (ex GST)	Product	
\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)	
\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)	
<b>\$20.56</b> Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)		
\$20.56	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)	
\$20.56	<b>NALOXONE SXP</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)	

#### **8 AUDIT REQUIREMENTS**

By participating in the THN Program, organisations recognise that providing false or misleading information is a serious offence and auditing of claims made under the THN Program may occur. Your organisation should therefore appropriately maintain all records (such as invoices and other supporting documents) related to the THN Program for seven years.

#### **9 REVIEW OF DECISIONS**

If you have any questions or do not agree with a decision made by the PPA in administering your claim for payment, please contact us at <a href="mailto:support@ppaonline.com.au">support@ppaonline.com.au</a> or on 1800 951 285. We'll check the decision, explain why we made the decision and ensure there aren't any errors. We aim to resolve matters quickly in line with the Program Rules set out in this document. A discussion explaining a decision is not a formal review.

#### **Formal review**

If you still disagree with the outcome, you can ask for a review of the decision. The review will be undertaken by the Department of Health and Aged Care, not the PPA, in accordance with the requirements set out in the *National Health (Take Home Naloxone Pilot) Special Arrangement Amendment (2022 Measures No. 1) Instrument 2022.* An application for review must be in writing to the Secretary of the Department of Health and Aged Care and importantly, in most circumstances the request for review must be made within 28 days after the decision came to your notice unless a longer period is allowed for by the Department of Health and Aged Care.

You can submit your formal request for a review by mail (GPO Box 9848, Canberra ACT 2601, Australia) or by email to <u>s100programs@health.gov.au</u>.

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#### APPENDIX A DATA COLLECTION FOR THE SUPPLY OF NALOXONE TO INDIVIDUALS

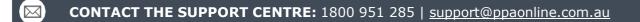
The following table indicates which organisations should collect the individual supply data outlined in Appendix A and confirms the method by which this data should be captured and reported.

Organisation	Data capture method	Submit data to:
Community (s90) pharmacies	PPA Portal	PPA
Public and Private Hospital (s94) pharmacies	PPA Portal	PPA
Approved (s92) Medical Practitioners	PPA Portal	РРА
AASs in WA	Information about required data capture will be provided to AASs by WA MHC	WA MHC
AASs in NSW and QLD and certain AASs in SA	PPA Portal	PPA
AASs in all other States and Territories	TBC by State/Territory	TBC by State/Territory
The required data set for each supply is	:	
Date of naloxone supply		
Formulations and quantities of n	aloxone supplied (maximum of two	0)
• Staff designation (e.g. Pharmaci	st, Social Worker)	
• Whether the individual consents	to the collection of de-identified in	nformation for program
monitoring purposes		
<ul> <li>If yes, whether the naloxone supplied was an initial supply or refill</li> </ul>		

- If refill, was the reason for refill:
  - My THN was used on me
  - My THN was used on someone else
  - My THN was given to someone else to keep
  - My THN is lost, damaged or expired.

This data is used to determine the appropriate payment rates for S90, S94 pharmacies, and s92 approved medical practitioners.

It is also used to allow the Commonwealth Government and State and Territory health departments to monitor the supply of naloxone under the Program.





#### APPENDIX B DATA COLLECTION FOR THE BULK SUPPLY OF NALOXONE TO AAS

Wholesalers, WA MHC and hospital (s94) pharmacies providing bulk supply of naloxone to AASs must supply to the PPA via the PPA Portal the following information for payment:

- Name of AAS naloxone supplied to
- Address of AAS naloxone supplied to
- Date of naloxone supply
- Staff designation (e.g. Pharmacist, Social Worker)
- Formulations, brands and quantities of naloxone supplied
- Invoice/Supporting evidence.

Please note the invoice/evidence uploaded must show all of the above information (other than the Staff Designation).

Rates of payment vary by organisation type and are summarised at Section 7, Fees.



#### **APPENDIX C PREVIOUS SUPPLY FEES**

#### C.1 Fees for supplies between 1 April 2023 and 30 June 2023

Payments under the program are made according to the PBS remuneration rates at the time the supply occurred, not the date the claim was lodged. Pricing for some naloxone preparations changed on 1 July 2023. The rates payable for supplies between 1 April 2023 and 30 June 2023 are provided below.

Please note NALOXONE SXP was not available under the THN Program until 1 August 2023 and is therefore not included in the tables below.

#### Table 9-1: Naloxone supply fees: Community (S90) Pharmacies

Individual Supply (ex GST)	Product
\$49.08	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$36.11	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$34.25	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$34.25	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

#### Table 9-2: Naloxone supply fees: Public Hospital (S94) Pharmacies

	Individual Supply (ex GST)	Bulk Supply (ex GST)	Product
<b>\$36.94 \$34.36 Nyxoid</b> (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)		Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)	
	<b>\$23.97 \$22.29 Prenoxad</b> (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)		
\$22.11\$20.56Naloxone Juno (naloxone hydrochloride 400 microgra 5x1 mL ampoules)		<b>Naloxone Juno</b> (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)	
	\$22.11	\$20.56	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

#### Table 9-3: Naloxone supply fees: Private Hospital (S94) Pharmacies

Individual Supply (ex GST)	Bulk Supply (ex GST)	Product	
\$45.28	\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)	
\$32.13	\$22.29	<b>Prenoxad</b> (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)	
\$30.24\$20.56Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)			
\$30.24	\$20.56	Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)	

#### Table 9-4: Naloxone supply fees: Approved Medical Practitioners (592)

Individual Supply (ex GST)	Product
\$49.08	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$36.11	<b>Prenoxad</b> (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$34.25	<b>Naloxone Juno</b> (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$34.25	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

#### Table 9-5: Naloxone supply fees: WA MHC and Wholesalers

Bulk Supply (ex GST)	Product
\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$20.56	<b>Naloxone Juno</b> (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$20.56	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

#### C.2 Fees for supplies between 1 July 2022 and 31 March 2023

Payments under the program are made according to the PBS remuneration rates at the time the supply occurred, not the date the claim was lodged. Pricing for some naloxone preparations changed on 1 April 2023. The rates payable for supplies between 1 July 2022 and 31 March 2023 are provided below.

# Individual<br/>Supply<br/>(ex GST)Product\$49.08Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)\$36.11Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)\$39.31Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL<br/>ampoules)\$39.31Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 microgram/mL<br/>injection, 5 x 1 mL ampoules)

#### Table 9-6: Naloxone supply fees: Community (S90) Pharmacies

#### Table 9-7: Naloxone supply fees: Public Hospital (S94) Pharmacies

Individual Supply (ex GST)	Bulk Supply (ex GST)	Product
\$36.94	\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$23.97	\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$27.17	\$25.27	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$27.17	\$25.27	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)

#### Individual Bulk Product Supply Supply (ex GST) (ex GST) Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation) \$45.28 \$34.36 \$32.13 \$22.29 **Prenoxad** (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe) Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, \$25.27 \$35.37 5x1 mL ampoules) Naloxone Hydrochloride (DBL) (naloxone hydrochloride 400 \$35.37 \$25.27 microgram/mL injection, 5 x 1 mL ampoules)

#### Table 9-8: Naloxone supply fees: Private Hospital (S94) Pharmacies

#### Table 9-9: Naloxone supply fees: Approved Medical Practitioners (S92)

Individual Supply (ex GST)	Product
\$49.08	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$36.11	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$39.31	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$39.31	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 × 1 mL ampoules)

#### Table 9-10: Naloxone supply fees: WA MHC and Wholesalers

Bulk Supply (ex GST)	Product
\$34.36	Nyxoid (naloxone 1.8 mg/actuation nasal spray, 2x1 actuation)
\$22.29	Prenoxad (naloxone hydrochloride 1 mg/mL injection, 2 mL syringe)
\$25.27	Naloxone Juno (naloxone hydrochloride 400 microgram/mL injection, 5x1 mL ampoules)
\$25.27	<b>Naloxone Hydrochloride (DBL)</b> (naloxone hydrochloride 400 microgram/mL injection, 5 x 1 mL ampoules)