Victorian guidance on patient delivered partner therapy (PDPT) for chlamydia

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OFFICIAL



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Purpose

This document provides health practitioners in Victoria with information about providing patient delivered partner therapy (PDPT) for the treatment of the sexual partners of patients with chlamydia. It includes guidance for prescribing PDPT, eligibility criteria, prescription documentation, compliance notes and practical information on how to implement PDPT within best-practice patient care.

These guidelines replace the following Department of Health (the department) 2015 documents:

- PDPT clinical guidelines
- · FAQs for clinicians
- Your partner has been diagnosed with chlamydia what now?

The department recommends that health practitioners who prescribe PDPT use this guidance document in conjunction with the key documents listed on page 9.

Background

Chlamydia trachomatis (chlamydia) is the most common notifiable sexually transmissible infection (STI) in Australia and the most commonly diagnosed bacterial STI worldwide. It is spread by having unprotected sex of any kind (vaginal, oral or anal) with an infected person.

If left untreated, chlamydia infections can cause serious long-term complications including chronic pelvic pain, pelvic inflammatory disease, ectopic pregnancy and infertility. If a pregnant woman has untreated chlamydia, it can be passed onto her baby during childbirth, causing lung or eye infections.

Over the past three decades, chlamydia notifications have dramatically increased in Victoria. In 2019, cases peaked and were 33 times higher than cases notified in 1991. From 2016 to 2021, a total of 137,587 chlamydia cases were notified in Victoria. Adolescents and young people carry the bulk of the infection burden, with most cases in the 20–29-year age range (median age 25 years). Nationally, the 5-year average of chlamydia cases (2016–2021) was 100,339 (Australian Government Department of Health 2021).

Partner notification

Informing (or notifying) and treating the sexual partner/s of people diagnosed with chlamydia helps to reduce the duration of infection for treated partner/s. This helps reduce ongoing transmission, the risk of reinfection for the index patient, and the risk of chlamydia-associated complications (such as pelvic inflammatory disease for women) for the index patient and their partner/s (Althaus et al. 2014; Reddel & Edmiston 2012). It is recommended that patients with a chlamydia infection inform their

¹ Victorian infectious diseases surveillance data is available online at https://www.health.vic.gov.au/infectious-diseases/infectious-diseases-surveillance-in-

² The decline in disease notifications observed in 2020 and 2021 should be interpreted with caution and are likely to under-represent true disease incidence.

Disease reductions are likely to be strongly influenced by the ongoing COVID-19 pandemic, resulting in changes in sexual behaviours, healthcare access, health seeking and testing practices and interstate and international travel restrictions.

partner/s from the preceding six months prior to diagnosis (Australasian Society for HIV Viral Hepatitis and Sexual Health Medicine [ASHM] 2016).

It is the responsibility of the diagnosing clinician to initiate a discussion with the patient about the need for partner notification, and to provide notification options, so the patient can make an informed decision about the most suitable option for each sexual partner (ASHM 2016). In most cases, the patient can do this. There are a range of options for the patient to do this such as by telling partners face-to-face or via online messaging or web-based services. These methods then require partners to seek treatment from a healthcare provider.

Patient delivered partner therapy (PDPT)

PDPT is a method of prescribing or providing antibiotic treatment for both the patient and their sexual partner/s. The patient then delivers a prescription, or the treatment, to their partner/s.

Recommended PDPT treatment

Azithromycin 1 gram given as a single oral dose of 2 tablets (500mg each).

Evidence for PDPT

Clinical trials have shown that PDPT with a single 1 gram dose of oral azithromycin for chlamydia, is a safe and effective method of treating sexual partners of people with chlamydia. There have been no serious adverse effects reported from azithromycin associated with PDPT (Golden et al. 2015; Schillinger et al. 2003; Trelle et al. 2007). PDPT has been demonstrated to treat more partners per case and to have a reduced risk of recurrent infection in the case than the patient advising their sexual partner/s to seek treatment. (Althaus et al. 2014; Golden et al. 2015; Schillinger et al. 2003; Trelle et al. 2007).

An evaluation of PDPT in Australia found that PDPT was acceptable to patients; 34 per cent of eligible patients were offered PDPT and 79 per cent of those accepted. Most partners who accepted PDPT were regular sexual partners (Lorch et al. 2019). Another Australian study found that 92 per cent of partners receiving PDPT took the antibiotics on the same day as the index case (Woodward et al. 2020). Further, an Australian survey of general practitioners (GPs) found that GPs accepted that PDPT is best targeted to partners who may not access timely testing or treatment and is more likely to be delivered in states and territories that provide clinical guidance (Goller et al. 2021).

PDPT safety

Azithromycin is a safe and well-tolerated antibiotic. The most commonly reported adverse effects include mild diarrhoea, nausea, vomiting, abdominal pain and dyspepsia (Hopkins 1991).

PDPT in Australia

PDPT is highlighted as an option in the *Fourth National Sexually Transmissible Infection Strategy* 2018–2022 (Australian Government Department of Health 2018), the *Australasian contact tracing* guidelines (ASHM 2016), the *Australian STI management guidelines: for use in Primary Care* (ASHM 2021) and the *Victorian sexually transmissible infections plan* 2022–30 (Department of Health 2022). The *Australasian Chapter of Sexual Health Medicine* (2009) has issued PDPT guidelines that outline patient selection, contraindications, recommended treatment and advice for prescribing and documentation.

At a jurisdictional level, PDPT for chlamydia infection is not prohibited under prescribing regulations in Victoria, and the prescription or supply of PDPT for chlamydia infection has been provided for in the Northern Territory and New South Wales (NT Department of Health 2014; NSW Government 2008; 2017).

PDPT in Victoria

In Victoria, the supply of Schedule 4 poisons (Prescription Only Medicines), including azithromycin, to a patient by a health practitioner, is governed by the Drugs, Poisons and Controlled Substances Act 1981 (the Act) and the Drugs Poisons and Controlled Substances Regulations 2017 (the Regulations). The Regulations do not prevent the prescribing or supply of PDPT.

In 2015, the department established formal PDPT clinical guidelines for chlamydia. This document provides an update to the 2015 guidelines and provides accompanying resources for health practitioners, patients and partners as follows:

- Appendix 1 PDPT clinical flowchart
- Appendix 2 PDPT prescription template
- Frequently asked questions (FAQs) (available on the <u>PDPT webpage</u>
 https://www.health.vic.gov.au/publications/patient-delivered-partner-therapy-clinical-guidelines).
 - FAQs for health practitioners
 - FAQs for patients
 - FAQs for partners.

Patient eligibility

Health practitioners should discuss a range of partner notification options with their patient (including PDPT) to ensure it is the correct option for the patient and partner. Further information about contact tracing can be found in the Australasian Contact Tracing Manual (see Key Documents below).

Patients eligible for PDPT:

- · only patients with a laboratory diagnosis of oral-pharyngeal or anogenital chlamydia
- heterosexual patients with partners who are unable or unlikely to attend a health service in a timely manner
- heterosexual patients with repeat infections whose partner/s have not been treated.

PDPT is not recommended for:

- patients diagnosed with chlamydia and other STIs (i.e., multiple STIs)
- patients whose partners who are pregnant. Azithromycin is safe in pregnancy, but pregnant people and their partners should see their doctor first to have other STIs excluded.
- · patients who have experienced recent sexual assault or may be at risk of partner violence
- patients or partner/s who may be at increased risk of HIV or other STIs such as men who have sex with men
- patients who have partners with any genital symptoms including symptoms of pelvic inflammatory disease or epididymitis.

Other considerations

It is possible that partners who use PDPT may be less likely to subsequently attend a health service for STI testing and clinical assessment. This means that their other partners cannot be advised of the need to seek treatment. It also means that co-infections and other related conditions, such as pelvic inflammatory disease, may be missed or have a delayed diagnosis. Due to this, PDPT is not recommended in populations with a high rate of HIV, such as men who have sex with men, and should be used with caution in populations with a high rate of gonorrhoea co-infection.

Prescribing or supplying PDPT

PDPT can be prescribed or supplied for any partner with whom the patient had unprotected sexual intercourse in the past six months. There is no limit to the number of partners for whom PDPT can be used.

There are many ways that a PDPT prescription can be provided. Some examples are provided in the table below. The method of generating the prescription will depend on whether the partner is a patient of the clinic or not, and on the processes established within a specific clinic.

Suggested methods of generating a PDPT prescription

Is the partner a patient of the clinic?	Method of generating prescription
Partner is an existing patient of the clinic	The prescription can be generated from and documented in the partner's electronic medical record
Partner is not an existing patient of the clinic	 Some suggested methods for writing the prescription include: handwritten on a paper prescription pad handwritten on prescription paper populated from a PDPT prescription template in the patient's medical record. A PDPT prescription template (see Appendix 2 for an example) can be imported into the letters section of the electronic medical software. Note: Prescriptions issued in this manner are private prescriptions and are not funded by the Pharmaceutical Benefits Scheme. This may have implications for Health Care Card holders. It should be documented in the patient's medical record that a PDPT prescription was provided.

The prescription should be provided to the patient with instructions that the prescription must be taken to a community pharmacy by the patient or partner.

Alternatively, health practitioners may supply a patient with the medication for them and their partner/s. Any medication supplied to a patient (including partner/s) must be labelled for that patient in accordance with the labelling requirements for a Schedule 4 poison. It should be accompanied by information resources for the patient and partner/s.

The required components of a label, which must not be less than 1.5 mm in size, on medicines dispensed by health practitioners, include:

 the approved name of the poison or controlled substance or a proprietary name that unambiguously identifies the poison or controlled substance plus the strength, form (for example, tablets) and quantity supplied

- · the words 'KEEP OUT OF REACH OF CHILDREN' in red on a white background
- · adequate directions for use
- the date on which supply is made or the dispensing is recorded. The date on which supply is
 made may differ from the date on which a medicine is dispensed, in anticipation of later
 supplying the medicine.
- · the name, address and telephone number of the practitioner supplying the medicine
- the name of the **person** for whom the medicine was dispensed.

Containers must be impervious to the contents, sufficiently sturdy to prevent leakage, and capable of being securely re-closed.

Information resources for patient and partner/s

It is recommended that health practitioners provide written information about PDPT for their patient and for each partner for whom PDPT is provided.

FAQs for patients and partners are available on the <u>PDPT webpage</u> https://www.health.vic.gov.au/publications/patient-delivered-partner-therapy-clinical-guidelines-and-include:

- instructions to deliver the prescription/dose to the partner/s
- · medication information about azithromycin
- · information about chlamydia
- · the means to seek health care
- the contact details of the health practitioner and clinic providing the prescription/dose.

It is important to advise all patients that there should be no sexual contact for seven days after treatment, and no sex with partners from the past six months until partners have been treated.

Documenting PDPT

In the patient's medical notes, record:

- · that PDPT was offered
- · if the patient accepted PDPT
- · the number of partners PDPT was accepted for, and each partner's name and address
- the PDPT method (prescription or supply)
- if the PDPT information sheet was provided for the patient and partner/s
- any relevant medical information known about the partner/s at the time of the consultation (this could be supported by a phone call to the partner/s)
- the method of writing the prescription (that is, if it was generated from electronic medical record [if a patient of the clinic], handwritten, or letter template).

Patient review/recommendations

Patients may be reviewed in one week to confirm patient adherence to treatment and partner notification. And support for partner management offered, if necessary.

A test of cure is not routinely recommended unless the patient is pregnant or the case has rectal chlamydia. Refer to relevant clinical guidelines in these instances.

As reinfection is common, patients should be recalled and retested in three months to test for reinfection. Testing for other STIs and HIV should also be considered if not undertaken at first presentation.

The recently updated *Australian STI Management Guidelines:* for use in primary care, recommends that all STI testing should include chlamydia, gonorrhoea, HIV and syphilis testing. The revised Standard Asymptomatic Check-Up https://sti.guidelines.org.au/standard-asymptomatic-checkup/ recommends asymptomatic STI checks for people who:

- request STI testing
- are at increased risk of STI (For example, have a new sexual partner or are living or travelling to areas of higher prevalence in Australia and other countries
- have a known exposure to any STI or history of an STI within the past 12 months
- are a partner of special subpopulation (For example, men who have sex with men, sex workers, pregnant people, Aboriginal and Torres Strait Islander people, trans and gender diverse people) or any of above. (ASHM, 2022).

Compliance aspects of PDPT in Victoria

Under the Regulations, medical practitioners and nurse practitioners must not administer, authorise administration, prescribe, sell or supply a Schedule 4 poison unless that poison is for the medical treatment of a person under his or her care; and that he or she has taken all reasonable steps to ensure a therapeutic need exists for that poison. The Department of Health provides guidelines – *All reasonable steps and other key terms: requirements for health practitioners* (see Key Documents below), to assist practitioners in complying with the Regulations.

The guidelines state:

Medical practitioners and nurse practitioners who prescribe or supply azithromycin, a Schedule 4 poison, to provide patient delivered partner therapy for a microbiologically confirmed chlamydia infection, generally will be considered to have satisfied the requirement (of regulations 17(c), 20(c), 36(b) or 39(b)) to take 'all reasonable steps' to ensure a therapeutic need exists, if they provide therapy in accordance with the Patient Delivered Partner Therapy Clinical Guidelines.

Under this PDPT guidance, the practitioner should assess the partner's symptom status, particularly symptoms indicative of a complicated infection, pregnancy status or risk of severe medication allergies. Practitioners should provide the patient with written information for the partner/s that includes consumer information about azithromycin, information about chlamydia, the means to seek health care and the contact details of the clinic providing the prescription. This information can be taken from the FAQs for patients and partners documents, available on the PDPT_webpage PDPT_webpage PDPT_webpage <a href="https://www.health.vic.gov.au/publications/patient-delivered-part

This PDPT guidance provides guidance in the use of PDPT but should not be considered as legal advice. If in doubt, the health practitioner should seek independent legal advice.

It should also be noted that practitioners have a duty of care to the partner/s of patients with a STI regardless of whether PDPT is used. This duty includes helping with contact tracing in situations where PDPT is not provided.

Key documents

- All reasonable steps and other key terms requirements for health practitioners
 https://www.health.vic.gov.au/publications/all-reasonable-steps-and-other-key-terms-requirements-for-health-practitioners
- <u>Drugs, Poisons and Controlled Substances Regulations 2017</u>
 https://www.legislation.vic.gov.au/in-force/statutory-rules/drugs-poisons-and-controlled-substances-regulations-2017/006
- Australian STI Management Guidelines for Use in Primary Care https://sti.guidelines.org.au/
- Australiasian Contact Tracing Manual http://contacttracing.ashm.org.au/

Appendix 1: PDPT clinical flowchart

This flowchart can be downloaded as a PDF or in accessible Microsoft Word format from the <u>PDPT webpage</u> https://www.health.vic.gov.au/publications/patient-delivered-partner-therapy-clinical-guidelines.

Patient with a positive chlamydia test

Index patient attends clinic for treatment of chlamydia (see <u>Australian STI Management Guidelines</u> https://sti.guidelines.org.au/).

Discuss notifying and managing sexual partners and suitability for PDPT

- · Partners from the past six months need to be notified and seek testing and/or treatment
- Health practitioners should discuss options for how to inform partner/s (for more partner notification information, see <u>Australasian Contact Tracing Manual http://contacttracing.ashm.org.au/)
 </u>
- Consider if PDPT is appropriate for the patient

Note: PDPT can be supplied for any partner with whom unprotected sexual intercourse occurred in the past six months.

PDPT recommended

- Heterosexual patients diagnosed with uncomplicated oropharyngeal or anogenital chlamydia whose partner/s are unable or unlikely to seek timely chlamydia testing and/or treatment
- Heterosexual patients diagnosed with repeat infection

PDPT not recommended

- · Patients diagnosed with chlamydia AND other STI
- Patients whose partners are pregnant*
- Patients who have experienced recent sexual assault or may be at risk of partner violence
- Patients or partners who may be at increased risk of HIV or other STI (e.g. men who have sex with men)
- · Partners with any genital symptoms

*Note: Azithromycin is safe in pregnancy, but pregnant people and their partners should see their doctor first to have other STI excluded.

Offer PDPT

- Explain and offer PDPT to patient
- Record PDPT offer in the medical record

PDPT accepted

PDPT not accepted

Do not offer PDPT

Continue with other partner management options

- Make a note in the patient's medical record that partner management was discussed
- Consider other options as per the Australasian Contact Tracing
 Manual

Note: Specialist clinical support is available via Health Pathways and Melbourne Sexual Health Centre.

Provide the patient with either a prescription for 1 gram azithromycin for the partner/s OR supply them with additional doses of 1 gram azithromycin to give to their partner/s

Provide information for patients and partner/s (see FAQs for patients and partners on the <u>main PDPT page</u> https://www.health.vic.gov.au/publications/patient-delivered-partner-therapy-clinical-guidelines) that summarises information about azithromycin, chlamydia, PDPT, contact details of the clinic providing the prescription and the means to seek healthcare.

Document PDPT

In the patient's medical notes, record:

- · patient accepted PDPT for their sexual partner/s
- number of partners PDPT was accepted for, each partner's name and address, and PDPT method (prescription or supply)
- · PDPT information provided for patient and their partner/s
- advice given that antibiotics should be taken immediately and to abstain from sex for seven days after taking
 the antibiotics

Note: If the partner is a patient of the clinic the prescription can be stored in the partner's medical record. If the partner is not a patient of the clinic the prescription can be handwritten or generated via a template in the index patient's electronic medical record. See Appendix 2 for a prescription template.

Patient review

- Review in one week to confirm patient adherence with treatment and partner notification
- · A test of cure is not routinely recommended, unless the patient is pregnant or has rectal chlamydia
- · Recall and retest patients in three months to detect reinfection. Consider testing for other STI and HIV
- Consider asymptomatic STI checks for people in accordance with the revised Australian STI Management Guidelines (see <u>Standard Asymptomatic Check-up</u> https://sti.guidelines.org.au/standard-asymptomatic-checkup/).

Appendix 2: suggested PDPT prescription template

The below template can be imported into the letter section of the clinic's electronic medical records software and then used to create a private script template for PDPT from the patient's medical record. <u>Download the template (in Rich Text Format) from the PDPT webpage</u> https://www.health.vic.gov.au/publications/patient-delivered-partner-therapy-clinical-guidelines

	Doctor Name
	Doctor Provider Number
	Doctor Full Address
	Doctor Phone No
Name (first and last)	[Insert the first and last name of the partner]
AND	
Address	[Insert the address of the partner]
Medication name and dose	Azithramyoin F00mg, 2 tablata
dose	Azithromycin 500mg, 2 tablets
	Take 2 tablets orally as a stat dose.
Signature	
Date	[insert date]

Prescriptions issued in this manner are private prescriptions and not funded by the Pharmaceutical Benefits Scheme (PBS).

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