

OCULAR THERAPEUTICS PROTOCOL - OPTOMETRISTS

I, Michael Reid, Chief Executive of Queensland Health, under the provisions of section 170 and Appendix 9 of the *Health (Drugs and Poisons) Regulation 1996*, approve the Ocular Therapeutics Protocol under which optometrists who have a prescribed qualification may obtain, possess, administer, supply or prescribe restricted drugs under the conditions stated in this protocol.

Background

Section 170(2) of the *Health (Drugs and Poisons) Regulation 1996* states:

- (2) To the extent necessary to practise optometry, an optometrist who has the prescribed qualifications is authorised to –
 - (a) obtain a registered restricted drug; or
 - (b) possess a registered restricted drug at the place where the optometrist practises optometry; or
 - (c) if the optometrist is reasonably satisfied a person needs a registered restricted drug for a therapeutic use as part of the person's ocular care or treatment, do any of the following under an ocular therapeutic protocol-
 - (i) administer or supply the drug to the person;
 - (ii) prescribe the drug for the person.

In section 170(3), a prescribed qualification is defined to mean the qualifications required under an ocular therapeutics protocol to administer, supply or prescribe a restricted drug.

Appendix 9 of the regulation defines an ocular therapeutics protocol as follows:

ocular therapeutics protocol means a document certified by the chief executive and published by the department stating –

- (a) the circumstances in which, and conditions under which, an optometrist may administer, supply or prescribe a restricted drug; and
- (b) the qualifications that an optometrist must attain before doing a thing mentioned in paragraph (a).

This protocol (including the “clinical pathways” - see 3.7) provides the framework for the professional use of prescription medications by optometrists in Queensland. Over time, as available prescription drugs and standards of care evolve, the protocol will be reviewed with the aim of ensuring it continues to be consistent with current knowledge and practice. Without appropriate training, this protocol is insufficient to successfully treat ocular disease. The clinical pathways are intended as guidelines and general principles to assist the optometrist in safely and effectively using certain drugs. They do not take the place of skilled clinical judgment.

This protocol is based on the document, *Ocular Therapeutic Protocol for Therapeutic Drug Use by Optometrists* published by the Optometrists Board of Queensland in June 2005, and the previously

published, “*Shared Care Protocol for Glaucoma Patients – Guidelines*” published by Queensland Health in January 2010.

1. Ocular Therapeutics - Legal Requirements

1.1 Prescribed qualifications

Optometrists may obtain, possess, administer, supply or prescribe a restricted drug specified in this protocol if they hold the prescribed qualification.

The aim of the training program leading to the prescribed qualification is to permit therapeutically qualified optometrists to:

- (i) have in their possession, administer, supply or prescribe (but not sell) topical ocular restricted drugs as required for the practice of optometry, and
- (ii) use those drugs appropriately for the treatment of ocular allergy, ocular infection, ocular inflammation, and toxic and traumatic conditions of the anterior eye.

The prescribed qualification is a scheduled medicines endorsement issued by the Optometry Board of Australia under section 94 of the *Health Practitioner Regulation National Law*.

This endorsement identifies programs of study that have been accredited by the Optometry Council of Australia and New Zealand and approved by the Board for the purpose of the endorsement. An optometrist may also hold an endorsement if they have successfully completed a program of study determined by the Board to be substantially equivalent to an approved program of study, or have successfully completed an examination or assessment in ocular therapeutics approved by the Board.

1.2 Restricted Drugs Permitted for Therapeutically-Qualified Optometrists

A therapeutically qualified optometrist is permitted to obtain, possess, administer, supply and prescribe only those restricted drugs for topical use specified by the Optometry Board of Australia in the scheduled medicines endorsement. The list of drugs may be updated by the Board periodically. The regulation permits optometrists to administer, supply or prescribe these drugs for ocular care or treatment only.

2. Requirements under the *Health (Drugs and Poisons) Regulation 1996*

2.1 Supply of Restricted Drugs by Therapeutically-Qualified Optometrists

The regulation does not authorise optometrists to dispense restricted drugs. The term ‘supply’ means to “give, or offer to give, a person one or more treatment doses of a drug, to be taken by that person during a certain period.” Optometrists may supply a restricted drug without charge but must not sell restricted drugs.

2.2 Prescribing Restricted Drugs by Therapeutically-Qualified Optometrists

Optometrists must take all reasonable steps to ensure a therapeutic need exists and prescribe, supply or administer drugs only for the ocular treatment of patients under their care. They must not write a prescription for use by anyone other than the patient named on the prescription.

Prescriptions must comply with section 190 of the regulation as summarised in the following paragraph.

Prescriptions must be handwritten (unless computer generated in a way authorised by the regulation), signed by the optometrist and include the following information on the front of the prescription –

- the prescriber's name, professional qualifications and address
- the date it is written
- the name and address of the person for whose use it is prescribed
- the description of the restricted drug and the quantity or volume (in figures) of the drug
- adequate directions about the use of the restricted drug
- the dose to be taken or administered
- a direction stating the number of times (after the first) the drug may be dispensed, and
- the statement - "For ocular treatment only"

The regulations do not allow optometrists to give oral prescriptions to the pharmacist (all prescriptions must be written).

If a restricted drug is supplied, including samples, the pack must be labelled with the details specified in section 198 of the regulation. All therapeutically-qualified optometrists need to be familiar with this section and the other requirements contained in the regulation.

2.3 Storage of Restricted Drugs

Storage of restricted drugs must comply with section 211 of the regulation. For example, drugs must be kept in a cupboard, dispensary, drawer, storeroom or other part of the place to which the public does not have access.

2.4 Records of Use of Restricted Drugs

Patient record cards must show the patient's name and address, the date, and the medication administered or supplied. Computer based records may be used.

Details of the supply or administration of restricted drugs must be carefully recorded and retrievable for a period of three years. Records must show the name of the prescriber. Filing carbon copies of prescriptions would be sufficient to meet this requirement.

3. General Guidelines for the Use of Restricted Drugs

3.1 Expectations of Therapeutically-Qualified Optometrists

The Optometry Board of Australia expects a standard of best practice from therapeutically-qualified optometrists in the diagnosis and management of eye disease. Practitioners should abide by their professional and ethical responsibilities as detailed in the Codes, Guidelines and Registration Standards, available on the Board's website.

3.2 Knowledge and Skills

Optometrists who prescribe, supply and administer restricted drugs are expected to have a clear understanding of microbiological and pathological processes relevant to eye disease, typical presentations of eye disease, their differential diagnoses and identification of risk factors.

Optometrists who prescribe, supply and administer restricted drugs are expected to have a sound knowledge of the pharmacology of these preparations, including:

- normal clinical response to their use
- indications and contraindications to use
- their potential side effects (topical and systemic)
- their interactions with other drugs, and
- how such complications can be avoided or managed.

Consulting room equipment should be commensurate with the ability to diagnose and monitor disease states. It is expected that optometrists would have access to equipment required for thorough assessment of anterior and posterior segments of the eye. It is expected that therapeutically-qualified optometrists will ensure their standard of care is appropriate. Their knowledge of relevant disease states and processes, together with the diagnosis and management of ocular disease, is expected to be current.

3.3 Clinical Assessment

Prior to initiating a patient on a course of restricted drugs, a thorough patient history must be taken to identify any factors that might predispose that individual to known side effects of drug use. This should be complemented by a thorough clinical examination to identify any factors that might contraindicate the use of such drugs.

3.4 Selection of Appropriate Restricted Drug

Selection of an appropriate drug requires consideration of many factors, including:

- clinical history, signs and symptoms of condition
- medical history (including current medications and known drug allergies)
- purpose of drug (prophylaxis vs. therapeutic)
- available preparations and their relative risk, benefit and efficacy
- potential drug interactions, and
- alternative (non-pharmaceutical) treatments, and their relative benefits and efficacy.

Practitioners must ensure that they do not use restricted drugs unless clinically indicated.

3.5 Patient Information and Review

Optometrists commencing patients on a course of restricted drugs should:

- advise patients of the nature of the preparation, the recommended dosage and when their optometric review appointment is scheduled
- perform regular reviews to monitor treatment efficacy
- identify any side effects and/or complications as they develop
- institute the necessary course of action to manage the patient's condition appropriately, and
- implement the plan after agreement with the patient.

3.6 Indications for Referral for Specialist Medical Treatment

Optometrists managing eye disease must be mindful of the potential complications of such conditions, have a clear understanding of when referral for specialist medical treatment is required and ensure, when such referral is indicated, that this occurs in a timely fashion.

3.7 Clinical Pathways

The purpose of the clinical pathways is to ensure high quality patient care and good clinical outcomes. The pathways are an important quality assurance mechanism leading to safe practice by optometrists. They outline the range of ocular conditions and the roles of optometrists in the delivery of therapeutic eye care. They are evidence-based management plans which describe a sequence of interventions and clinically appropriate care, allowing always for the place of clinical judgement in that care. Therapeutically-qualified optometrists will have acted in accordance with the protocol if they treat and/or manage a patient's ocular condition in line with the relevant clinical pathway, or in another way that is appropriate for the person's ocular care.

4. Shared Care Protocol for Glaucoma Patients

Therapeutically qualified optometrists may also co-manage glaucoma patients in a shared care arrangement with an ophthalmologist in accordance with the Shared Care Protocol For Glaucoma Patients (Attachment 1). The anti-glaucoma drugs specified by the Optometry Board of Australia in its scheduled medicines endorsement apply for the purposes of this protocol.

Signed at Brisbane on this 2nd day of November 2010.

Michael Reid
Chief Executive
Queensland Health

ATTACHMENT 1: SHARED CARE PROTOCOL FOR GLAUCOMA

Under these guidelines suitably trained optometrists who are approved to use therapeutic drugs in their practices will be able to co-manage glaucoma patients in a shared care arrangement with an ophthalmologist.

Management of glaucoma patients typically includes:

- evaluation of intraocular pressures, visual fields and ocular structures;
- instigation of the necessary therapeutic and/or surgical treatment at the appropriate time;
- ongoing review to monitor for any changes in ocular status (including progression of the disease and/or side effects of treatment); and
- alteration to treatment strategies if required (this may include changes in medication regimens, surgical intervention or other alterations).

Once the diagnosis of glaucoma is confirmed by the ophthalmologist and a treatment plan is in place for the patient, the optometrist can perform ongoing reviews to monitor the patient and prescribe topical drugs providing that:

- periodic review demonstrates the treatment to be effective;
- changes to management are only initiated following consultation between treating Ophthalmologist and treating Optometrist and where appropriate, patient's usual General Practitioner;
- the Ophthalmologist will remain responsible for clinical management.

Initial Referral to Ophthalmologist

An optometrist who makes a provisional diagnosis of glaucoma is to refer the patient to an ophthalmologist for confirmation of the diagnosis, initiation of treatment and the development of a management plan to allow for the patient's ongoing treatment. The referral should preferably be to their usual treating ophthalmologist.

Where clinically important delays are expected before the patient's first review by an ophthalmologist, the optometrist should seek interim advice from the ophthalmologist by telephone on the patient's management, and arrange an appointment with the ophthalmologist as soon as possible.

The patient's consent is to be obtained by the ophthalmologist and the optometrist for all aspects of the management plan, including the sharing of care between the two practitioners.

Patients being considered for anti-glaucoma therapy with a beta-blocking agent should be assessed for any potential cardio-vascular or respiratory risk by a medical practitioner (often the patient's General Practitioner) prior to initiating therapy. This assessment should be repeated if a change of dose of the beta-blocker is proposed.

Patient Management Plan

After confirmation of initial diagnosis and once the patient is stable a management plan will be written by the Ophthalmologist and should include the following:

1. All the agreed components of treatment including any drug therapy.
2. Target pressures and any action to be taken if target pressures are not achieved within a specified time frame.

3. An agreed approach to monitoring visual fields and Optic Disc Imaging and the action to be taken following changes in visual fields.
4. What changes in visual function and/or ocular status will trigger referral for more immediate ophthalmologic review (this might include guidelines for referral based on Intraocular Pressure (IOP) levels, visual fields, optic nerve head appearance *and/or* other risk factors).
5. Likely side effects from agreed treatment and the action to be taken to address those side effects.
6. An agreed schedule for patient review by both the ophthalmologist and the specific optometrist, designating who is responsible for ensuring the patient attends agreed follow up visits (in most cases a patient will have a review by an ophthalmologist at least once per year).
7. Who is responsible for performing each of the required tests (including visual fields and mydriatic disc examination) and how frequently these tests must be done.
8. How clinical findings are communicated between parties, including General Practitioners, and mechanisms employed to ensure ongoing, open communication between all the practitioners involved. Ophthalmologists must be available for consultation by the treating optometrist and for consultation by the patient where that consultation has been recommended or requested by the optometrist.
9. This plan needs to be reviewed on an annual basis.
10. Copies of the plan should be given to the General Practitioner, Optometrist and the patient.

In an emergency, an ophthalmologist can be contacted through the Royal Brisbane and Women's Hospital or the Princess Alexandra Hospital switchboard.