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Royal Cornwall Hospitals NHS Trust

Orthoptists Medical Exemptions Clinical Guideline

V1.0

March 2023

Summary

This guidance applies to orthoptists who are annotated with the Health and Care Profession Council (HCPC) as having access to Section 17 Exemptions under the Human Medicines Regulations 2012. It describes how they are able to supply and administer listed Prescription-Only Medicines (POMs) and Pharmacy (P) medicines while working for the Royal Cornwall Hospitals NHS Trust.

1. Aim/Purpose of this Guideline

1.1. The objective of this policy is to provide guidance for orthoptists on the administration of medicines covered by S17 exemptions, including the appropriate indications and clinical circumstances where each medicine can be used.

1.2. The aim is to ensure that all legal and statutory requirements regarding prescribing, supply, and administration of medicines are met.

1.3. This policy applies to patients under the care of HCPC-registered orthoptists working for the Royal Cornwall Hospitals NHS Trust.

1.4. Under the Human Medicines Regulations 2012 (HMR), registered orthoptists may administer or supply on their own initiative any of the POMs that are specified in Schedule 17 (S17), provided it is in the course of their professional orthoptic practice.

1.5. Exemptions are listed under Part 3 of S17 HMR. In addition, part 4 of S.17 HMR allows the sale and supply of a medicines that are on the General Sales List (GSL) or Pharmacy-only (P) medicines.

1.6. Medicines covered by these exemptions may be supplied or administered without the need for a prescription or patient specific direction (PSD) from a medical practitioner or non-medical prescriber. Provided the conditions attached to these exemptions are met, a patient group direction (PGD) is not required. If a medicine is not included in the orthoptist's exemptions, or the conditions attached to its use cannot be met, then a prescription, PSD, or PGD will be required to enable the orthoptist to supply or administer it.

1.7. Registered orthoptists must only supply and administer those medicines in which they have received the appropriate training as regards the therapeutic use, dosage, side effects, precautions, contra-indications, and methods of administration.

1.8. Orthoptists must only supply or administer medicines when they have personally assessed the patient and there is a genuine clinical need for the use of the medicine.

1.9. Student orthoptists can only administer medicines listed on the orthoptist exemptions list under the direct supervision of a registered orthoptist who holds a recognised qualification to use S17 exemptions.

Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1. To provide support and guidance to orthoptists in the supply and administration of drugs that are listed under orthoptists' exemptions as specified in S17 of the HMR 2012.

2.2. This policy applies to the supply or administration of medication to all patients seen within the Ophthalmology services provided by the Royal Cornwall Hospitals NHS Trust.

2.3. The supply or administration of medication under the orthoptist exemptions must be by a qualified orthoptist to eligible patients treated within the Ophthalmology Service. All medication supplied or administered must be included in the Trust Formulary.

2.4. The orthoptist must be registered with the Health Care Professions Council (HCPC) and must be employed by the Royal Cornwall Hospitals NHS Trust. Administration or supply must be made within the course of orthoptic professional practice i.e., the patient must be known to the orthoptist making the supply.

2.5. Orthoptists qualified prior to 2020 must have completed an HCPC-approved medical exemption course and gained the annotation to their HCPC registration.

2.6. Orthoptists who qualified in 2020 onwards will have HCPC-approved exemptions as part of their degree qualification but must also have gained the annotation to their HCPC registration.

2.7. The orthoptist is professionally accountable for their decision regarding the supply and administration of medicines under exemptions, including actions and omissions.

2.8. Orthoptists supplying or administering medication under orthoptists exemptions must ensure that their practice is up to date and that they are familiar with the medicines that they supply. They should have access to current versions of the British National Formulary (BNF) and the British National Formulary for Children (BNFC). They must be aware of the indications, side effects and contra-indications for any medication supplied or administered. The current versions of the BNF and BNF-C are available online at www.medicinescomplete.com

2.9. Orthoptic exemptions

The following medication may be supplied or administered as an orthoptist exemption (if available) (See Appendix 3 for drug information).

Drug name and Form	Legal class	Route	Indication
Cyclopentolate hydrochloride 0.5% and 1% single-use eye drop	POM	Topical	To produce mydriasis and cycloplegia
Tropicamide 0.5 % and 1% single-use eye drop	POM	Topical	To produce mydriasis and cycloplegia
Atropine Sulphate 1% single-use eye drop	POM	Topical	To produce mydriasis and cycloplegia
Fluorescein sodium 2% single-use eye drop	P	Topical	Fluorescence of corneal or conjunctiva
Phenylephrine hydrochloride 2.5% and 10% single-use eye drop	P	Topical	To produce mydriasis
Lidocaine hydrochloride 4% w/v fluorescein sodium 0.25% single-use eye drop	POM	Topical	Local anaesthetic and fluorescence of the corne
Oxybuprocaine 0.4% single-use eye drop	POM	Topical	Local anaesthetic
Proxymetacaine hydrochloride 0.5% single-use eye drop	POM	Topical	Local anaesthetic
Tetracaine hydrochloride 0.5% single-use eye drop	POM	Topical	Local anaesthetic
Chloramphenicol 0.5% single-use eye drop	POM	Topical	Antimicrobials

Drug name and Form	Legal class	Route	Indication
Fusidic acid 1% eye drops	POM	Topical	Antimicrobials
Ocular lubricants	P, GSL or Medical Device	Topical	Dry eye

Orthoptists may only supply or administer a medicine under a S17 exemption if it is listed in this policy.

2.10. Assessment

2.10.1. The orthoptist must complete a full assessment of the patient, including a thorough history and accessing a full clinical record (where possible) including their medication and allergy history

2.10.2. An orthoptist should only supply or administer medicines when they have relevant knowledge of the patient's health and medical history commensurate with this decision

2.10.3. The patient's current medication and any potential interactions with other medicines should be considered

2.11. Consent

2.11.1. The orthoptist must ensure the patient (or their representative, for patients lacking capacity to consent) understands the treatment and can give appropriate informed consent. The patient or their representative must be given sufficient information relating to the potential risks, benefits and outcomes of the treatment considered as well as the comparative risks and benefits of alternative treatment options

2.11.2. The patient has the right to refuse the supply or administration of any medicine. If they do so, you should ensure they are aware of the risks, benefits, and outcomes of their decision. This should be documented in the patient's clinical record

2.12. Administration and supply

Prior to administering or supplying a medication using a S17 exemption, the orthoptist will need to ensure that:

- There is a genuine clinical need
- They have up to date knowledge of the medication they are supplying / administering
- The patient is known to them, and that administration is within the course of their professional practice

- The patient is not allergic to the medication or any of its excipients
- The patient has no contra-indications to the proposed medication
- The medication proposed is the most appropriate choice for the required indication
- The patient is counselled on any medication they are given in terms of indication, use and side effects

2.13. Documentation

2.13.1. All supply or administration of medicines should be recorded in the clinical records at the time of administration or supply.

2.13.2. Records must include details of the medicines supplied and/or administered, together with relevant details or the consultation with the patient. This should include the site of administration and the expiry date and batch number of the medicines supplied or administered.

2.13.3. For every medicine administered, the orthoptist must ensure that the patient electronic records are accurate, and that the patient's allergy status is recorded or updated.

2.14. Information given to patients

2.14.1. Patients or their representatives should be given as much information as they require in order for them to make an informed choice with regard to using medicines. This information should be sufficient for the patient to use the medicine safely and appropriately. The patient should be advised on what to do if their condition worsens or fails to improve and advised if they need to avoid certain activities such as driving.

2.14.2. The appropriate Patient Information Leaflets should be supplied. These are enclosed in the packaging of the medicine and should not be removed.

2.15. Roles and Responsibilities of Orthoptists

2.15.1. Each registered orthoptist is accountable for their own conduct and practice in accordance with the HCPC 'Standards of conduct, performance and ethics 2016'.

2.15.2. Each orthoptist is responsible for their decision to supply or administer any medicine using a S17 exemption in accordance with this policy.

2.15.3. Any orthoptist supplying and administering under an orthoptist exemption is required to have up to date knowledge for that medication with regards to:

- Indication
- Dosage
- Side effects
- Precautions
- Contraindications
- Method of administration
- This will be demonstrated by:
- Adhering to the ‘Practice Guidance for orthoptist for the supply and administration of medicines under Exemptions’
- Completing a HCPC-approved S17 Exemptions Programme and having the annotation on the HCPC register as qualified to use S17 exemptions
- Orthoptists are responsible for:
- Adhering to the list of agreed S17 exemptions within this policy
- Ensuring the safe and clinically appropriate use of medicines
- Ensuring their practice and knowledge is up to date by accessing appropriate resources (e.g., BNF, BNFC)
- Discussing the risks and benefits of any drug treatment administered or supplied to their patient and obtaining informed consent to do so

3. Monitoring Compliance and Effectiveness

3.1. Clinical audit

3.1.1. The supply or administration of medicines to patients using S17 exemptions will be audited to ensure they have been successfully managed within the orthoptic pathway

3.1.2. The patients who have responded to treatment should be monitored. Patients who do not attend for their appointments should be contacted by telephone or letter

3.2. Learning from incidents and errors

3.2.3. Orthoptists should record all incidents and/or error with using the Trust incident reporting system (Datix) to facilitate national reporting where required

3.2.4. Any incidents should be reviewed within the orthoptic and ophthalmology teams, alongside the Medicines Practice Committee to enable learning and changes in practice where necessary

3.2.5. Adherence to this policy will be audited and any deviations from policy reported and investigated via Datix

3.3. Continuing Professional Development

Orthoptists should:

- Remain up to date with appropriate knowledge and skill to enable them to supply and administer medicines competently and safely within their scope of practice
- Ensure that the CPD undertaken is in line with current practice or future practice, including any extended roles undertaken

3.4. Review

Review required on three yearly basis or earlier if legislation changes.

3.5. Approval

Ophthalmology Business and Governance Meeting, Care Group Board, Medicines Practice committee.

Information Category	**Detail of process and methodology for monitoring compliance**
Element to be monitored	All Orthoptists Medical exemptions
Lead	Faye Gibson (Head Orthoptist)
Tool	Exemptions document on orthoptic shared drive
Frequency	Every 3 years
Reporting arrangements	Report to be presented at orthoptic staff meeting. Outcome recorded in the minutes for the meeting
Acting on recommendations and Lead(s)	Faye Gibson (Head orthoptist) will undertake subsequent recommendations and action planning
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within6 weeks. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant colleagues

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Orthoptists Medical Exemptions Clinical Guideline V1.0
This document replaces (exact title of previous version):	New Document
Date Issued/Approved:	21 March 2023
Date Valid From:	March 2023
Date Valid To:	March 2026
Directorate / Department responsible (author/owner):	Wendy Reynolds, Lead Orthoptist for Glaucoma
Contact details:	01872 253287
Brief summary of contents:	Guidance for orthoptists (with a medical exemption qualification) on the administration and supply of medicines
Suggested Keywords:	Orthoptist, medical exemption
Target Audience:	RCHT: Yes CFT: Yes CIOS ICB: No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Medication Practice Committee
General Manager confirming approval processes:	Roz Davies
Name of Governance Lead confirming approval by specialty and care group management meetings:	Maria Lane
Links to key external standards:	**References** Medicines for Human Use Regulations (2012) The Human Medicines (Amendment) Regulations 2016 (legislation.gov.uk) NHS England – Use of

Information Category	Detailed Information
	exemptions within the Human Medicines Regulations 2012 by Orthoptists. HCPC Standards of conduct, performance, and ethics standards-of-conduct-performance-and-ethics.pdf (hcpc-uk.org) Outline Curriculum Framework for Education Programmes to prepare Orthoptists to use Exemptions final-pg-for-website-aug-17.pdf (orthoptics.org.uk) University of Liverpool Clinical Tutors Handbook 2018-19pdf British National Formulary (BNF), Feb 2019, accessed via www.medicinescomplete.com
Related Documents:	Amblyopia guidelines Glaucoma surveillance clinic standard operating procedure
Training Need Identified?	Yes – orthoptists to complete HCPC approved medical exemptions qualification and gain the relevant annotation to their HCPC registration.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Ophthalmology

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
21 March 2023	V1.0	Initial issue	Wendy Reynolds Lead Orthoptist for Glaucoma

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Orthoptists Medical Exemptions Clinical Guideline V1.0
Directorate and service area:	Ophthalmology (surgical)
Is this a new or existing Policy?	New
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Faye Gibson
Contact details:	01872 253287

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Orthoptists with the relevant medical exemptions' qualification
2. Policy Objectives	Guidance for orthoptists (with a medical exemption qualification) on the administration and supply of medicines
3. Policy Intended Outcomes	To enable orthoptists, with the relevant medical exemption qualification, to supply/ administer a specific list of medicine
4. How will you measure each outcome?	3 yearly audits
5. Who is intended to benefit from the policy?	Orthoptists, Ophthalmologists, and patients

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: Yes • External organisations: Yes • Other: Yes
6b. Please list the individuals/groups who have been consulted about this policy.	Orthoptic colleagues Ophthalmologists Pharmacy
6c. What was the outcome of the consultation?	To develop a policy to provide guidance and structure for orthoptists working with medical exemptions
6d. Have you used any of the following to assist your assessment?	No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Faye Gibson, Head Orthoptist

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis