Royal Cornwall Hospitals
NHS Trust

Glycopyrronium in Children Shared Care Guideline

V3.0

November 2023

1. Aim/Purpose of this Guideline

1.1. This guideline applies to medical, nursing and pharmacy staff in the safe and appropriate prescription and administration of glycopyrronium in children.

1.2. This shared care guideline sets out details for the sharing of care of children suffering from sialorrhoea prescribed **glycopyrronium** (also known as glycopyrrolate). This guideline provides additional limited information necessary to aid in the treatment of these patients. As with all shared care guidelines it highlights relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and **does not** replace them.

1.3. This version supersedes any previous versions of this document.

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

The Trust has a duty under the Data Protection Act 2018 and UK 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 UK 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 UK 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. Indication

Sialorrhoea, or drooling, affects approximately a third of patients with cerebral palsy, but is also associated with a number of chronic childhood disorders. Excessive drooling has both medical and social implications. In severe cases drooling can cause skin irritation, infection and dehydration, and therefore medical intervention becomes necessary. Drooling can be caused by poor swallowing mechanisms as well as excessive saliva production. Current drug treatment for the condition aims to dry up secretions, hence reducing drooling. Saliva production and secretion is thought to be controlled by the parasympathetic nervous system via muscarinic receptors, and therefore antimuscarinic drugs, such as glycopyrronium, have become the treatment of choice. It should be noted that these drugs do not stop drooling completely but can reduce the symptoms that patients experience. Glycopyrronium is one of the best tolerated antimuscarinic agents. It does not cross the blood brain barrier easily. This means that the central effects, such as drowsiness and confusion, are less pronounced than with other antimuscarinic agents, such as hyoscine. It also has a much longer half life than other antimuscarinic drugs, and therefore

needs to be taken less frequently.

2.2. Glycopyrroniun is given by the oral route for control of upper airway secretions and hypersalivation.

2.3. Preparation and Dosage For All Indications

2.3.1. Sialanar 320 micrograms /ml oral solution is the preferred product. This is a licensed glycopyrronium formulation for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. Each ml contains 400 micrograms glycopyrronium bromide equivalent to 320 micrograms of glycopyrronium.

2.3.2. Sialanar is a sugar free, raspberry flavoured liquid medicine, which comes in a 250ml bottle with an oral dosing syringe. The medicine has been tested for use with PEG and NG feeding tubes. When administering the medicine via these tubes, a 10ml flush of water should follow afterwards. Sialanar requires no special storage conditions and must be discarded 2 months from opening.

2.3.3. Prior to Sialanar being licensed, other products listed below (unlicensed or off label) were used and some children may still be receiving these products. If appropriate, patients receiving these other products below may be switched to Sialanar in general practice ensuring that the correct dose of Sialanar is prescribed noting the strength when expressed as glycopyrronium bromide or glycopyrronium, and patient/carer are fully informed of the switch.

2.3.4. Glycopyrronium bromide 1mg and 2mg tablets are licensed for symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. For patients who cannot swallow tablets, other pharmaceutical forms should be used.

2.3.5. Unlicensed oral solution / suspension of glycopyrronium bromide have also been prescribed.

2.3.6. Glycopyrronium bromide doses vary widely as patient response is so variable. The usual dose range is 40-100 micrograms/kg given 3-4 times a day. The patient will have received at least one month’s treatment, been shown to respond to the treatment and the dosage stabilised before it is requested that prescribing responsibility is transferred to the GP. In some patients tolerance to glycopyrronium may develop requiring the dose to be increased. If tolerance does develop the patient should be referred back to the specialist team.

2.4. Monitoring

There are no specific monitoring requirements.

2.5. Contraindications And Precautions

Glycopyrronium will not be prescribed in:

- Hypersensitivity to the active substance or to any of the product's excipients listed in
- Pregnancy and breast-feeding.
- Glaucoma.
- Urinary retention.
- Severe renal impairment (eGFR <30 ml/min/1.73m2), including those with end-stage renal disease requiring dialysis.
- History of intestinal obstruction, ulcerative colitis, paralytic ileus, pyloric stenosis and myasthenia gravis
- Concomitant treatment with potassium chloride solid oral dose or anticholinergics
- Caution should be exercised when prescribing glycopyrronium in patients with either renal or hepatic impairment.
- Glycopyrronium may antagonise pro-motility drugs such as domperidone and metoclopramide, so should be used with caution in patients taking these drugs.
- Topiramate: glycopyrronium may potentiate the effects of oligohidrosis and hyperthermia associated with the use of topiramate, particularly in pediatric patients;
- Opioids: active substances such as pethidine and codeine may result in additive central nervous system and gastrointestinal adverse effects, and increase the risk of severe constipation or paralytic ileus and CNS depression. If concomitant use cannot be avoided, patients should be monitored for potentially excessive or prolonged CNS depression and constipation;
- Medicinal products with anticholinergic properties (e.g. antihistamines, antidepressants) may cause cumulative parasympatholytic effects including dry mouth, urinary retention, constipation and confusion, and an increased risk of anticholinergic intoxication syndrome.

2.6. Side Effects

2.6.1. The side effects of glycopyrronium are predictable, reversible and arise from the drug's mode of action. Typical antimuscarinic effects include:

- Tachycardia, hypotension, cardiac arrhythmias.
- Constipation, oesophageal reflux, dry mouth.

- Blurred vision, pupilary dilation, raised intraocular pressure.
- Drowsiness, headache, dizziness.
- Hallucinations, confusion, insomnia, tremor.
- Fever caused in part by reduced sweat production.

2.6.2. These side effects are not dose related and there is significant variation in tolerability to the drug between patients. The rate of side effects is high (32-69% of patients), but these adverse reactions are rarely severe. However, up to 35% of patients and their families will choose to stop therapy due to these adverse effects.

2.6.3. There have been occasional reports of allergic reactions to glycopyrronium, including anaphylaxis.

2.7. Areas of Responsibility for the Sharing of Care

2.7.1. These are suggested ways in which the responsibilities for the management of children who are prescribed glycopyrronium can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP, and patient. The intention to share care should be explained to the patient and be accepted by them.

2.7.2. In the NHSE guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

2.7.3. Referral criteria:

Glycopyrrolate will be initiated by the consultant in patients with severe drooling. The patient will have received at least one month's treatment, been shown to respond to the treatment and the dosage stabilised, before prescribing is transferred to the GP.

2.7.4. Specialist responsibilities:

- Make any necessary diagnoses and communicate these to the GP and other professionals involved in the patient's care.
- Discuss the treatment options with the patient, their parent(s) and carer(s). A patient information leaflet is attached in the Appendix 4 of this document.
- Asking General Practitioners (GP) if they are willing to participate in shared care using the suggested wording template (Appendix 3).

- Continuing need for prescription to be reviewed at least annually.
- Communicate any changes, recommendations, changes, outcomes, or other important information to the GP.
- Provide advice to the GP if they have clinical queries relating to the underlying condition or use of glycopyrronium.
- Take back care of the patient should the GP feel unable to continue to manage the prescribing of glycopyrronium.

2.7.5. General Practitioner responsibilities:

- To respond to the shared care request from the consultant in writing without undue delay.
- Accept the request to continue prescribing of glycopyrrolate within the boundaries of this shared care protocol, for which prescribing responsibilities will commence 4 weeks from the date of reply.
- Prescribe appropriate quantities for the patient on a regular basis.
- Carry out further dose titration according to the specified schedule, or discontinue the medication, when necessary or requested.
- Communicate any problems to the Specialist looking after the patient.
- Only ask the Specialist to take back the prescribing should unmanageable problems or tolerance to the drug develop and allow an adequate notice period (4 weeks is a suggested minimum).

2.7.6. Patient and parent / carer responsibilities:

- Report any concerns or adverse effects to the GP, Specialist or Pharmacist.
- Patient information leaflet can be found as an Appendix to this document.

BACK-UP ADVICE AND SUPPORT IS AVAILABLE FROM THE RELEVANT CLINICAL TEAM.

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice).
Lead	Head of Prescribing Support Unit.
Tool	Adherence to guidelines will be monitored as part of the ongoing audit process within the department on a Word or Excel template specific to the topic.
Frequency	As required according to clinical incident reports.
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee.
Acting on recommendations and Lead(s)	Relevant Clinical Staff.
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff.

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 Diversity And Inclusion 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:	Glycopyrronium in Children Shared Care Guideline V3.0
This document replaces (exact title of previous version):	Shared Care Guideline for glycopyrrolate V2.1
Date Issued/Approved:	November 2023
Date Valid From:	November 2023
Date Valid To:	November 2026
Directorate / Department responsible (author/owner):	Community Paediatric Team / Pharmacy - Head of Prescribing Support Unit.
Contact details:	01872 253548
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists.
Suggested Keywords:	Glycopyrronium, Glycopyrrolate, Shared Care.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee. Care Group Governance.
Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming consultation and ratification:	Kevin Wright
Links to key external standards:	None indicated
Related Documents:	1. BNF. 2. BNF for Children. 3. Summary of Product Characteristics. www.medicines.org.uk

Information Category	Detailed Information
	4. Medicines for Children. www.medicinesforchildren.org.uk
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
November 2013	V1.0	New version in this format	Mike Wilcock, Head of Prescribing Support Unit
September 2014	V1.1	Minor amendment to tablet availability	Mike Wilcock, Head of Prescribing Support Unit
September 2017	V1.2	New date of approval	Mike Wilcock, Head of Prescribing Support Unit
November 2020	V2.0	New version in this format. Glycopyrrolate name changed to glycopyrronium. Branded Sialanar included	Mike Wilcock, Head of Prescribing Support Unit
September 2021	V2.1	Replacement of shared care agreement letter with suggested wording template instead (Appendix 3).	Mike Wilcock, Head of Prescribing Support Unit
November 2023	V3.0	Mention of licensed tablets at 2.3.4	M Wilcock and Community Paediatric team

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

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). 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:	Glycopyrronium in Children Shared Care Guideline V3.0
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow
Contact details:	01872 253548

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)	To provide information on prescribing of glycopyrronium to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area).
3. Policy Intended Outcomes	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure each outcome?	Six monthly review.
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

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: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Cornwall Area Prescribing Committee.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** 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	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
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: Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow.

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

Appendix 3. Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment).

Baseline tests: (insert information).

Next review with this department: (insert date).

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

Appendix 4. Glycopyrronium – Information for patients, parents, and carers

Your child has been prescribed glycopyrronium, which helps to reduce secretions. It is being used to reduce drooling.

hat is glycopyrronium?

Glycopyrronium is a known as an ‘anticholinergic’ or ‘antimuscarinic’.

How should glycopyrronium be taken?

Glycopyrronium is usually given by mouth 3-4 times each day, although the dose needed varies as each child responds differently to the medication. Your child may also need larger doses as treatment continues because in some cases the body may become tolerant to the effects of the glycopyrronium, and therefore more glycopyrronium is needed to get the same effects.

Glycopyrronium is available as a liquid oral solution.

Does glycopyrronium have any side effects?

Along with its needed effects glycopyrronium can cause side effects, such as dry mouth, thirst, blurred vision, confusion, difficulty urinating (passing water) and mood changes. These side effects may ease as your child continues to take glycopyrronium. However, if these symptoms continue and become troublesome discuss them with your doctor.

Rarely, glycopyrronium can cause allergic reactions resulting in difficulties in breathing and skin rashes. If you think your child is having an allergic reaction stop the drug and seek medical advice straight away.

Does glycopyrronium interact with other medicines?

Glycopyrronium has not been found to affect any other medication. However, other medications that have antimuscarinic effects, such as some antihistamines, should be avoided if possible as these may increase the risk of side effects. If you have any concerns, please discuss these with your GP or pharmacist.

Does glycopyrronium require a doctor’s prescription?

Yes. In the UK, glycopyrronium products are only available on a doctor’s prescription.

How will the pharmacist obtain glycopyrronium?

Your local pharmacy will be able to obtain supplies as below:

Sialanar is the brand name, and each ml contains 400 micrograms glycopyrronium bromide equivalent to 320 micrograms of glycopyrronium.

Where can I obtain further information?

You can obtain further information from your consultant.