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Royal Cornwall Hospitals NHS Trust

Pharmacological Agents for use in Adults with Parkinson's Disease with Sialorrhea – Prescribing and Shared Care Guideline

V1.0

May 2022

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 pharmacological agents for the purpose of minimizing symptoms of sialorrhea in adults with Parkinsonism causing excessive drooling.

1.2. This guideline sets out details for the sharing of care of adults with excessive drooling and to empower primary care practitioners to commence pharmacological therapy for excessive drooling where they feel able to do so, thereby minimizing any delays to treatment. This guideline provides additional limited information necessary to aid in the treatment of these patients. As with all shared care and prescribing guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and do not replace them.

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

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. Antimuscarinics or anticholinergic medications, used in the management of sialorrhea in patients with Parkinson's syndromes, (as well as cerebral palsy, motor neurone disease or other conditions with secondary hypersalivation which are not specifically dealt with in this guideline).

2.2. Xeomin® brand of botulinum toxin A has a licensed indication for treatment, every 4 months (treatment interval of no less than 16 weeks), and should be offered as first line pharmacological treatment in some patients for whom there is a significant impact on quality of life but for whom pharmacological agents are contraindicated, unsuitable, undesirable, too risky or ineffective. Use of other preparation of botulinum toxin type A is off-label. This service is currently operating at capacity, but this guideline will be updated to include more information as capacity is expanded.

2.3. Drug Treatment Recommendations

2.3.1. Glycopyronium Bromide may be used for the treatment of excessive drooling. It is unlicenced by NICE for this indication in adults and therefore the recommendation of this guideline is for 'off label' use. This can be initiated, continued or discontinued either autonomously from primary care or with outside advice.

2.3.2. Where requiring advice from secondary care, contact:

2.3.2.1. RCHT silver phone Telephone: 01872 252161- this provides access to the on-call Consultant Geriatrician and is available 08.00h – 20.00h seven-days per-week,

2.3.2.2. Advice and guidance through the eldercare department; https://rms.kernowccg.nhs.uk/primary_care_clinical_referral_criteria/primary_care_clinical_referral_criteria/eldercare/rcht_eldercare_advice_and_guidance_

2.3.2.3. Nurse lead community Parkinson's team pdnurses.cornwall@nhs.net

2.3.3. Only consider pharmacological management for drooling of saliva in people with Parkinson's disease if non-pharmacological management (for example, speech and language therapy) is not available or has not been effective. It is recommended therefore that patients are assessed and managed via the non-pharmaceutical pathway before this treatment should be initiated.

2.3.4. In patients for whom the criteria highlighted in 2.3 have been met, parallel referral for assessment in Xeomin clinic should be considered and offered for those who would so wish. This pathway is, at present undefined due to lack of provision, and will be revised in coming months. Until then there is a service operated in Cornwall via Neurology outpatients *rcht.neurology@nhs.net* or via Maxillofacial surgery outpatients rch-tr.Oralsurgerymedsecs@nhs.net *01872 253986.*

2.3.5. In certain circumstances alternative agents such as 1% atropine eye drops administered sublingually or transdermal hyoscine hydrobromide may be prescribed when treatment including dosage has already been established and has been deemed to be successful with tolerable side effects. Due to the risk of side effects in what can be summarised as an older frail population of patients suffering with excessive drooling, we would not recommend a new trial of these agents due to high side effect burden in our patient population.

2.3.6. For patients in whom active saliva reduction with glycopyrronium or Xeomin offers a tangible improvement in quality of life with minimal side effects long term treatment should be accompanied by vigilant oral hygiene, with regular dental appointments and good mouth hygiene being essential.

2.4. Preparations and Dosage

2.4.1. Glycopyronium Bromide 400 micrograms/ml Oral Solution* is to be commenced at a dose of 1ml (400mcg) orally, one to three times daily; this should then be titrated to effectiveness and tolerability. Limited evidence from literature[1] in this patient cohort suggests a reasonable dose in order to achieve efficacy would be in the region of 2ml or 800mcg Sialanar (equivalent to 640mcg glycopyrronium) TDS. Dose titration should be continued until efficacy is balanced with undesirable effects and amended up or down as appropriate to a maximum individual dose of 6ml, 2.4 mg, (equivalent to 1.9 mg glycopyrronium), not exceeding three times a day. Dose titrations should be conducted in discussion with the patient and or carer to assess both efficacy and undesirable effects until an acceptable maintenance dose is achieved – see monitoring section 2.6 for further advice.

2.4.2. It is important to ensure that glycopyrronium is stored as per manufacturers recommendations.

2.4.3. The patient will have received at least four weeks treatment, been shown to respond to the treatment clinically at an established dosage & the frequency of administration clarified before monitoring can be stepped down.

2.4.4. Please ensure that patient's other medication has been reviewed for potential interactions in line with the BNF guidance and SPC (see appendix 5)

2.4.5. Glycopyronium bromide is also available in a tablet form which may be suitable

* Sialanar 320 micrograms/ml oral solution. Each ml contains 400 micrograms of glycopyrronium bromide equivalent to 320 micrograms of glycopyrronium

[1] Arbouw MEL, Movig KLL, Koopmann M et al. Glycopyrrolate for sialorrhea in Parkinson disease: a randomized, double-blind, crossover trial. Neurology 2010;74:1203-1207.

2.5. Contraindications and Precautions*

2.5.1. Absolute Contraindications are:

- Dementia
- eGFR <30

2.5.2. Relative Contraindications** are:

- Angle closure glaucoma
- Myasthenia Gravis
- Poor oral hygiene / dental caries
- Postural Hypotension

- Frequent delirium attacks
- Urine retention
- Concurrent use of antimuscarinics
- Tachyarrhythmia
- High alcohol consumption
- Poor oral hygeine
- Other less common conditions
    - gastro-intestinal obstruction
    - intestinal atony
    - paralytic ileus
    - pyloric stenosis
    - severe ulcerative colitis
    - significant bladder outflow obstruction
    - toxic megacolon.

*For a full list if concerned please refer to BNF.

**There is a theoretical risk of worsening the above conditions, in the case of angle closure glaucoma, myasthenia gravis and urine retention specifically, unchecked administration may lead to permanent complications and will depend on overall risk benefit stratification taking into account factors such as diagnostic certainty, pharmacological responsiveness, disease stability and patient wishes.

2.5.3. **Caution**

- Glycopyronium may result in thick harder to clear secretions in those with chronic mucinous cough.
- Can increase constipation or cause diarrhoea.
- Anticholinergic effects such as urinary retention, constipation and overheating due to inhibition of sweating may be dose dependent and difficult to assess in frail elderly or multimorbid. Monitoring by physicians and caregivers is required with adherence to the management instructions below:

The carer should stop treatment and seek advice from the prescriber in the event of:

- Oral thrush or dental problems

- constipation
- urinary retention
- pneumonia
- allergic reaction
- pyrexia
- very hot weather
- changes in behaviour

After evaluating the event, the prescriber will decide if treatment should remain stopped or if trial of lower dose could be considered whilst remaining effective.

- Sialanar has moderate influence on the ability to drive and use machines. The anticholinergic effects of glycopyrronium may cause blurred vision, dizziness and other effects that may impair a patient's ability to perform skilled tasks such as driving, riding a bicycle and using machines. The undesirable effects are increased with increasing dose.

2.6. Monitoring

2.6.1. Specialist Team

- Use of drooling severity scale helps quantify effect of medication – see appendix 2
- In conjunction with GP can make recommendations or adjustments to prescription based on side effects and whether a desired outcome has been achieved.
- In either case of treatment failure or success consideration for early referral for Xeomin / salivary botulinum toxin A injections is prudent. There is likely to be a significant wait for this.

2.6.2. General Practice

- Can issue patients with drooling severity scale questionnaire to fill out and adjust dosage to patient tolerance and desired effect.
- There are no specific biochemical monitoring requirements for the GP to undertake.
- It is advisable to routinely check renal function in those patients taking regular Glycopyronium with a baseline eGFR <40, the frequency of checks will depend on the pattern of renal function.
- Blood pressure monitoring should ideally incorporate a postural component.

- Emphasise the importance of regular dental check up

2.7. **Side Effects**

This is not an exhaustive list – full list of side effects may be found in the patient information leaflet or BNF

- New confusion or drowsiness (an effect exacerbated by the consumption of alcohol)
- Dry mouth with or without worsening dysphagia
- Urinary retention
- headaches
- vomiting
- Tachyarrhythmia
- diarrhoea or constipation
- blurry vision are possible side effects of the medication
- hyperthermia and heat stroke in hot environments (decreased sweating)
- Postural hypotension

2.8. **Significant Drug Interactions**

- Anticholinergic medication
- Ipratropium or Glycopyronium inhaler

2.9. **Areas of Responsibility for the Sharing of Care**

2.9.1. These are suggested ways in which the responsibilities for the management of patients with chronic neurological disorders suffering from excessive drooling who are prescribed Glycopyronium bromide liquid 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.

2.9.2. **In the NHS E-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.**

2.9.3. **Specialist:**

- Communicate relevant clinical observations to the GP and other professionals involved in the patient's care
- Discuss the treatment options with the patient, and carer(s), to include explanation of the nature of Glycopyronium, obtaining appropriate consent to treatment and to share care with the GP. Patient information leaflet for Glycopyronium may be found at pil.2301.pdf (medicines.org.uk)
- Initiate treatment with glycopyrronium if agreed and titrate the dose and frequency to a satisfactory effect over a minimum of 4 weeks.
- Ask the GP whether they are willing to participate in shared care using the suggested wording template (Appendix 3). This letter should include full clinical details
- If commencing Glycopyronium in out-patient in outpatient clinic insure the patient has at least 2 weeks medication providing enough time for the referral letter to reach GP– and for the GP accepting the request to continue prescribing.
- Ensure the patient is fully aware of the need to obtain a prescription from their GP for delivery to their chosen community pharmacy or from the dispensing surgery so that arrangements can be made to obtain stocks
- Follow up every 4 – 6 months to ensure continuing benefit of glycopyrronium
- Ensure that the appropriate monitoring (of subjective benefit with aid of drooling severity scale and any new side effects are documented for monitoring or consideration to stop) is undertaken.
- Undertake periodic treatment review, and advise of the intended frequency.
- Communicate any changes, recommendations, outcomes or other important information to the GP
- Provide advice to the GP if they have clinical queries relating to the condition or use of glycopyrronium
- Take back care of the patient should the GP feel unable to continue to manage the prescribing of glycopyrronium

2.9.4. **General Practitioner:**

- To respond to a consultant shared care request from the in writing without undue delay.
- If in receipt of a advice to consider treatment from another health professional (eg SALT) please initiate as per guidelines below or make a prompt onward referral to the specialist team if you feel this is outside your remit or competence.
- When accepting the request to continue prescribing of Glycopyronium, to do so within the boundaries of this shared care protocol – prescribing responsibilities will commence 4 weeks from the date of reply
- When commencing a prescription for glycopyrronium discuss the treatment options with the patient, and carer(s), to include explanation of the nature of glycopyrronium bromide, obtaining appropriate consent to treatment. Patient information leaflet for glycopyrronium bromide may be found at pil.2301.pdf (medicines.org.uk)
- Initiate treatment with glycopyrronium if agreed and titrate the dose and frequency to a satisfactory effect over a minimum of 4 weeks.
- Ensure that the appropriate monitoring (of subjective benefit with aid of drooling severity scale and any new side effects are documented for monitoring or consideration to stop) is undertaken.
- Carry out further dose & frequency of administration adjustment when indicated or as suggested by the specialist, or discontinue the medication, when necessary or requested
- Seek advice from the specialist via advice and guidance, community nurse specialist or silverphone at Treliske if they have clinical queries relating to the condition or use of Glycopyronium
- Communicate any problems to the Consultant looking after the patient
- Only ask the Consultant to take back the prescribing should unmanageable problems arise and allow an adequate notice period (4 weeks is a suggested minimum)

2.9.5. **Patient / parent / guardian / carer:**

- Agree to request prescriptions from the GP in good time; obtain the first GP prescription within 2 weeks of being informed that shared care will be in operation and make an appointment to have the injection sufficiently early
- Stick with one chosen community pharmacy unless there are good

reasons to change, or from a dispensing surgery for a dispensing patient.

- Report any concerns or adverse effects to the GP, Consultant or Pharmacist

- Patient information leaflet for glycopyrronium can be found pil.2301.pdf (medicines.org.uk) Whilst described for use in children it remains relevant.

2.9.6. **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	Audit and review tool using patient documentation.
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, Inclusion & 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:	Pharmacological Agents for use in Adults with Parkinson's Disease with Sialorrhea – Prescribing and Shared Care Guideline V1.0
This document replaces (exact title of previous version):	New Document
Date Issued/Approved:	April 2022
Date Valid From:	May 2022
Date Valid To:	May 2025
Directorate / Department responsible (author/owner):	Neurology / Elderly Care / Pharmacy Mike Wilcock, 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 bromide
Target Audience:	RCHT: Yes CFT: No KCCG: No
Executive Director responsible for Policy:	Medical Director
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None required
Related Documents:	Resource for Doctors and Patients: pharmacological-management-of-non-motor-symptoms

Information Category	Detailed Information
	Glycopyrrolate for sialorrhea in Parkinson disease **A randomized, double-blind, crossover trial** M.E.L. Arbouw, K.L.L. Movig, M. Koopmann, P.J.E. Poels, H.-J. Guchelaar, T.C.G. Egberts, C. Neef, J.P. P. van Vugt Neurology Apr 2010, 74 (15) 1203-1207; DOI: 10.1212/WNL.0b013e3181d8c1b7
Training Need Identified?	Yes
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
January 2022	V1.0	Initial Issue	M Simms. ST7 Eldercare. RCH

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 & Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Pharmacological agents for use in sialorrhea Use Prescribing and Shared Care Guideline V1.0
Directorate and service area:	Pharmacy
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):	Dan Thomas, Pharmaceutical Services Contracting Team, NHS Kernow
Contact details:	01726 627953

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 Pharmacological agents for use in sialorrhea to enable General Practitioners both to initiate and 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. Drooling Severity and Frequency Scale (DSFS) 26

The Drooling Score equals the sum of the Severity and Frequency sub-scores.

Drooling Severity Scale

1 = Never drools, dry

2 = Mild-drooling, only lips wet

3 = Moderate- drool reaches the lips and chin

4 = Severe- drool drips off chin & onto clothing

5 = Profuse- drooling off the body and onto objects (furniture, books)

Drooling Frequency Scale

1 = No drooling

2 = Occasionally drools

3 = Frequently drools

4 = Constant drooling

- If this scale can't be used a self-rating of symptoms can also be useful (how bad is your drooling mild moderate / severe).
- A repeat scale can be done after 2 weeks therapy if there is uncertainty of effect, and should be done as part of the 1 month assessment of efficacy/tolerability.

Appendix 4. 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 5. Summary of Product Characteristics ‘Sialanar’ / Glycopyronium Bromide 400mcg/ml

Electronic medicines compendium reference
Sialanar 320 micrograms/ml Glycopyrronium (400 micrograms/ml Glycopyrronium Bromide) Oral Solution

Sialanar 320 micrograms/ml Glycopyrronium (400 micrograms/ml Glycopyrronium Bromide) Oral Solution - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)