East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG, Surrey Heath CCG, Crawley CCG, Horsham & Mid-Sussex CCG
Evidence review for Prescribing Clinical Network

Medicine and proposed indication	Sialanar® 320 micrograms/ml Glycopyrronium (400 micrograms/ml Glycopyrronium Bromide) Oral Solution for Sialorrhoea (chronic pathological drooling) in children **This paper does not review the use of glycopyrronium in adults**
Requested by	Medicine Management Team (Hosted Service) on behalf of its users, following ePact interrogation of prescription habits

SUMMARY

Clinical Effectiveness

NICE Evidence Summary ES5 - Severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide. Published 14 February 2017[1].

A literature search was conducted by NICE which identified 62 references (see search strategy for full details). These references were screened using their titles and abstracts and 11 references were obtained and assessed for relevance.

Two randomised controlled trials (RCTs) identified from the search (Mier et al. 2000 and Zeller et al. 2012a) were included in this evidence summary.

- This evidence summary discusses 2 small randomised controlled trials (RCTs) that compared glycopyrronium bromide with placebo for the treatment of severe sialorrhoea in children and young people with chronic neurological conditions. The majority of participants had cerebral palsy.
- In both RCTs, participants treated with glycopyrronium bromide had statistically significantly improved drooling after 8 weeks, (measured using the modified Teacher's Drooling Scale [mTDS]), compared with placebo.
- Adverse effects were common with glycopyrronium bromide, mostly due to its anticholinergic action. The most commonly reported adverse effects include dry mouth, constipation, urinary retention, reduced bronchial secretions and flushing. The SPC advises that glycopyrronium bromide can cause thickening of secretions, which may increase the risk of respiratory infection and pneumonia. Glycopyrronium bromide should be used with caution in people with heart problems due to its potential increase in heart rate, blood pressure and rhythm disorders (SPC: glycopyrronium).
- There is a lack of long-term safety data for glycopyrronium bromide, and the SPC recommends that the total treatment duration should be kept as short as possible.
- It is not possible to determine the relative effectiveness of glycopyrronium bromide compared with other treatments for severe sialorrhoea because glycopyrronium has only been compared to placebo. Because Sialanar is not bioequivalent to other formulations of glycopyrronium bromide, switching to Sialanar should only be conducted under supervision to ensure that efficacy and side effects are balanced. The effectiveness of glycopyrronium bromide should be balanced against the adverse effects associated with treatment.

The remaining 8 references were excluded. These are listed under excluded studies in the NICE paper with reasons for their exclusion.

Comment: There are no randomised controlled comparative studies, so prescribers should consider evidence for effectiveness, potential side effects and available routes of administration when choosing between them. The absence of long-term studies means that there is no evidence for continued effectiveness or safety if used continuously for long periods[6].

Safety

The Sialanar® SPC states that adverse effects are common with glycopyrronium bromide due to its anticholinergic action. The most common adverse reactions include dry mouth, constipation, diarrhoea, urinary retention, flushing and nasal congestion[4].

The SPC advises that anticholinergic adverse effects may be dose dependent and difficult to assess in a child with disabilities. Treatment should be stopped in the event of constipation, urinary retention or pneumonia[4].

Due to the lack of long term safety data, Sialanar® is recommended for short-term intermittent use only[4].

Summary of Product Characteristics (SPC) for this product[4] specifically states the following:

- **Mild to moderate sialorrhoea:** Due to the low likelihood of benefit and the known adverse effect profile, Sialanar® should not be given to children with mild to moderate sialorrhoea.
- **Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in [SPC]. Pregnancy and breast-feeding. Glaucoma. Urinary retention. Severe renal impairment (eGFR <30ml/min/1.73m2) including those with end-stage renal disease requiring dialysis. History of intestinal obstruction, GORD, ulcerative colitis,

paralytic ileus, pyloric stenosis and myasthenia gravis. Concomitant treatment with potassium chloride solid oral dose; anticholinergics; and cardiac conditions.

Glycopyrronium bromide was associated with more adverse effects and discontinuations because of adverse effects than placebo[1].

Patient factors

- Glycopyrronium bromide was associated with more adverse effects and discontinuations because of adverse effects than placebo[1].
- The SPC recommends that glycopyrronium bromide should be taken at least one hour before or at least two hours after meals or at consistent times with respect to food intake[1].
- Most children in the clinical trials had cerebral palsy. Glycopyrronium has not been extensively tested in children with other neurological conditions[1].

Cost implications

- Glycopyrronium bromide tablets and oral solution are available on prescription, but previously these have been imported or prepared by "specials" manufacturers at fluctuating and uncontrolled cost to the NHS.
- Glycopyrronium bromide oral solution (Colonis®) and tablets (multiple companies) are now available and is licensed for use in adults as an add-on therapy in the treatment of peptic ulcer (use in sialorrhoea would be off-label).
- From Aug-15 to Jul-16, prescribing costs for oral Glycopyrronium bromide (all formulations, all indications, all patient groups) was as follows:-

CCG	Cost	Cost per 100,000 pop.
East Surrey CCG	£58,034.46	£32,028.37
Guildford & Waverley CCG	£38,529.48	£17,149.36
Surrey Downs CCG	£97,583.90	£31,934.72
Surrey Heath CCG	£8,943.33	£9,307.92
North West Surrey CCG	£86, 290.86	£23,385.81

- Glycopyrronium bromide 400 microgram/ml oral solution (Sialanar) costs £320 per 250 ml bottle (MIMS, February 2017). At a dose of 1,600 micrograms (4 ml) three times daily the 28-day cost is £430.08 (based on a child weighing 33 kg at a dose of 48 micrograms/kg glycopyrronium bromide)[1].
- Once opened the bottle has a shelf life of 28 days. Any liquid remaining after this time should be discarded[1].
- The manufacturer estimates that there are approximately 1,500 children in England who may be eligible for treatment with glycopyrronium bromide[4].
- Unfortunately, current prescribing data within the PCN is not specific to indication or patient group, so generalisations of cost pressures/savings have been made. But if calculated by presuming that all current prescribing is for the patient group under consideration, and an average cost per item prescribed of £305, and presuming that was for a 28-day supply, then the use of Sialanar would be a cost pressure to the CCGs of £83k per annum on current prescribing costs.

It should be noted, that it is thought that the majority of current prescribing of Glycopyrronium bromide is for adult patients (an off-label use of this product and not considered as part of this review).

Relevant guidance / reviews

1. **Severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide (NICE Evidence Summary 5)[1]**

Glycopyrronium bromide (Sialanar) is an antimuscarinic (anticholinergic) medicine licensed in September 2016 for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. Sialanar is licensed for short-term intermittent use and is only licensed in children. There is limited clinical trial evidence on the use of glycopyrronium in adults with sialorrhoea. Sialanar 320 micrograms/ml oral solution is the first formulation of glycopyrronium bromide licensed for this indication in the UK.

This evidence summary discusses 2 small randomised controlled trials (RCTs) that compared glycopyrronium bromide with placebo for the treatment of severe sialorrhoea in children and young people with chronic neurological conditions. The majority of participants had cerebral palsy.

In both RCTs, participants treated with glycopyrronium bromide had statistically significantly improved drooling after 8 weeks, (measured using the modified Teacher's Drooling Scale [mTDS]), compared with placebo.

Adverse effects were common with glycopyrronium bromide, mostly due to its anticholinergic action. The most commonly reported adverse effects include dry mouth, constipation, urinary retention, reduced bronchial secretions

and flushing. The SPC advises that glycopyrronium bromide can cause thickening of secretions, which may increase the risk of respiratory infection and pneumonia. Glycopyrronium bromide should be used with caution in people with heart problems due to its potential increase in heart rate, blood pressure and rhythm disorders (SPC: glycopyrronium).

There is a lack of long-term safety data for glycopyrronium bromide, and the SPC recommends that the total treatment duration should be kept as short as possible.

It is not possible to determine the relative effectiveness of glycopyrronium bromide compared with other treatments for severe sialorrhoea because glycopyrronium has only been compared to placebo. Because Sialanar is not bioequivalent to other formulations of glycopyrronium bromide, switching to Sialanar should only be conducted under supervision to ensure that efficacy and side effects are balanced. The effectiveness of glycopyrronium bromide should be balanced against the adverse effects associated with treatment.

Likely place in therapy relative to current treatments

Other medicines that have been used to manage sialorrhoea include the following (Specialist Pharmacy Service, 2015):

- other antimuscarinic medicines (for example hyoscine hydrobromide, amitriptyline, atropine and trihexyphenidyl hydrochloride)
- beta-blockers (for example, propranolol)
- botulinum toxin[1].

None of these medicines are licensed in the UK for managing sialorrhoea and their use would be off-label.
None of these medicines are currently recommended for use in sialorrhoea within PCN.

In line with the guidance from the General Medical Council (GMC), unlicensed or off-label medicines should be used only where there is no suitably licensed medicine that will meet the patient's need.
This would mean that Sialanar should be considered as the first-line option for children and young people with sialorrhoea (as it is currently the only available product with this specific licence), before the off-label use of licensed products.

Recommendation to PCN

Blue with information sheet

Glycopyrronium to be initiated by the consultant in paediatric patients with severe drooling who have tried other antimuscarinic treatments but have found these therapies are inadequate or intolerable due to side effects.
The specialist should provide care and prescription until the patient is at a stable dose, and clear instructions should be provided to the GP at point of transfer with regards to dose changes, and the monitoring and management of anticholinergic side-effects.
For consideration by the members:

- PCN members to advise if the committee wishes to state which treatment/s must be used prior to glycopyrronium e.g. Scopaderm TTS, oral hyoscine or atropine etc.
- PCN to make recommendation as to whether patients currently using the unlicensed products are to be switched to the licensed product (noting that Sialanar is not bioequivalent to other formulations of glycopyrronium bromide, switching to Sialanar should only be conducted under supervision to ensure that efficacy and side effects are balanced. The effectiveness of glycopyrronium bromide should be balanced against the adverse effects associated with treatment.)[1]

Medicine details	
Name and brand name	Glycopyrronium (400 micrograms/ml Glycopyrronium Bromide) Oral Solution –licensed in children (Sialanar®320microgram/ml)
Licensed indication, formulation and usual dosage	Glycopyrronium 2mg in 5ml oral solution (Sialanar®) for **Symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.** **Paediatric population** – children and adolescents aged 3 years and older The dosing schedule for glycopyrronium is based on the weight of the child, starting with approximately 12.8 micrograms/kg per dose (equivalent to 16 micrograms/kg per dose glycopyrronium bromide), three times per day and increasing by the doses shown in Table 1 below, every 7 days. 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 64 micrograms/kg body weight glycopyrronium or 6 ml (1.9 mg glycopyrronium,

	equivalent to 2.4 mg glycopyrronium bromide) three times a day, whichever is less. Dose titrations should be conducted in discussion with the carer to assess both efficacy and undesirable effects until an acceptable maintenance dose is achieved. Undesirable effects may be minimised by using the lowest effective dose necessary to control symptoms. It is important that the carer checks the dose volume in the syringe before administration. The maximum volume of the highest dose is 6ml. In the event of a known anticholinergic adverse event occurring when the dose is increased, the dose should be reduced to the previous lower dose and the event monitored. If the event does not resolve treatment should be discontinued. In the event of constipation, urinary retention or pneumonia treatment should be stopped and the prescribing physician contacted. Younger children may be more susceptible to adverse events and this should be borne in mind when any dose adjustments are carried out. Following the dose titration period, the child's sialorrhoea should be monitored, in conjunction with the carer at no longer than 3 monthly intervals, to assess changes in efficacy and/or tolerability over time, and the dose adjusted accordingly. The Table 1 shows the dose in ml of solution to be given for each weight range at each dosing increase. Table 1. Dosing table for children and adolescents with normal renal function. **Weight Kg** / **Dose Level 1 (~12.8µg/kg)[1]** / **Dose Level 2 (~25.6µg/kg)[1]** / **Dose Level 3 (~38.4µg/kg)[1]** / **Dose Level 4 (~51.2µg/kg)[1]** / **Dose Level 5 (~64µg/kg)[1]** — all in ml 13-17: 0.6 / 1.2 / 1.8 / 2.4 / 3 18-22: 0.8 / 1.6 / 2.4 / 3.2 / 4 23-27: 1 / 2 / 3 / 4 / 5 28-32: 1.2 / 2.4 / 3.6 / 4.8 / 6* 33-37: 1.4 / 2.8 / 4.2 / 5.6 / 6 38-42: 1.6 / 3.2 / 4.8 / 6* / 6 43-47: 1.8 / 3.6 / 5.4 / 6 / 6 ≥48: 2 / 4 / 6* / 6 / 6 refers to µg/kg glycopyrronium *Maximum individual dose in this weight range[4]
Summary of mechanism of action, and relevant pharmacokinetics	The salivary glands are innervated by the sympathetic and parasympathetic nervous system. Parasympathetic postganglionic cholinergic nerve fibres stimulate the rate of salivary secretion[2]. Glycopyrronium bromide is an antimuscarinic drug that can potentially reduce salivary secretions. Antimuscarinics are contra-indicated in GI obstruction, intestinal atony, myasthenia gravis (but some antimuscarinics may be used to decrease muscarinic side-effects of anticholinesterases), paralytic ileus, prostatic enlargement, pyloric stenosis, severe ulcerative colitis, significant bladder outflow obstructions, toxic megacolon and urinary retention[1].
Important drug interactions	Concomitant use of the following medicinal products is contraindicated: **Potassium chloride solid oral dose**: glycopyrronium may potentiate the risk of upper gastrointestinal injury associated with oral solid formulations of potassium chloride due to increased gastrointestinal transit time creating a high localized concentration of potassium ions. An association with upper GI bleeding and small bowel ulceration, stenosis, perforation, and obstruction has been observed. **Anticholinergics**: concomitant use of anticholinergics may increase the risk of anticholinergic side effects. Anticholinergics may delay the gastrointestinal absorption of other anticholinergics administered orally and also increase the risk of anticholinergic side effects. Concomitant use of the following medicinal products should be considered with caution: **Antispasmodics**: glycopyrronium may antagonize the pharmacologic effects of gastrointestinal prokinetic active substances such as domperidone and metoclopramide. **Topiramate**: glycopyrronium may potentiate the effects of oligohidrosis and hyperthermia associated with the use of topiramate, particularly in pediatric patients;

	Sedating antihistamines: may have additive anticholinergic effects. A reduction in anticholinergic and/or antihistamine dosage may be necessary; **Neuroleptics/antipsychotics**: the effects of active substances such as phenothiazines, clozapine and haloperidol may be potentiated. A reduction in anticholinergic and/or neuroleptic/antipsychotic dose may be necessary; **Skeletal muscle relaxants**: Use of anticholinergics after administration of botulinum toxin may potentiate systemic anticholinergic effects; **Tricyclic antidepressants and MAOIs**: may have additive anticholinergic effects. A reduction in anticholinergic and/or tricyclic antidepressants and MAOIs dosage may be necessary. **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; **Corticosteroids**: Steroid-induced glaucoma may develop with topical, inhaled, oral or intravenous, steroid administration. Concomitant use may result in increased intraocular pressure via an open- or a closed-angle mechanism; **Other 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[4].
Monitoring requirements	Anticholinergic effects such as urinary retention, constipation and overheating due to inhibition of sweating may be dose dependent and difficult to assess in a disabled child. Monitoring by physicians and caregivers is required with adherence to the management instructions below: **Management of important anticholinergic side effects** The carer should stop treatment and seek advice from the prescriber in the event of: • 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 this should continue at a lower dose[4].
Prescribing considerations	If the indication is sialorrhoea, then prescriptions should be made by brand name, i.e. Sialanar®
Other considerations	Current practice to treat sialorrhoea in children is likely to be as recommended in NICE guideline NG62 (Cerebral palsy in under 25s: assessment and management)[6] and is believed to be the off-label use of oral anticholinergics, beta-blockers and botulinum toxin. It is to be noted that in line with the guidance from the General Medical Council (GMC), unlicensed or off-label medicines should be used only where there is no suitably licensed medicine that will meet the patient's need. Sialanar® is the only licensed product available at this time.

Potential patient group (if appropriate to include)	
Brief description of disease	• Hypersalivation is the excessive production of saliva. This presents as drooling in children, young people and adults with a neurological condition, such as cerebral palsy, or Parkinson's disease. • Hypersalivation can also be an adverse effect of drug treatment (e.g. clozapine). • Chronic drooling can be defined as the unintentional loss of saliva from the mouth. Drooling is normal in infants and it usually stops by 15-18 months or age, but is considered pathological if present after 4 years. • Drooling is usually present due to neurological disturbance and less frequently to overproduction of saliva. Under normal circumstances, persons are able to compensate for increased salivation by swallowing. • However, sensory dysfunction may decrease a person's ability to recognise drooling

	and autonomic or motor dysfunction of swallowing may impede the ability to manage increased secretion[3]. • Drooling can result in perioral chapping, irritation, maceration and secondary infection of the skin. • Drooling is thought to result in oropharyngeal dysfunction, including reduced swallowing frequency[1]. • Bird et al (2011) reported that, second to sedation, hypersalivation is one of the most common adverse effects attributed to clozapine, occurring in 30-80% of people taking the drug[1].
Potential patient numbers per 100,000	The prevalence of moderate to severe drooling in children, young people and adults with neurological conditions, particularly cerebral palsy is estimated to be between 10 and 37%[1].
Outcomes required	Reduction on drooling and the resultant effects of drooling.

Summary of current treatment pathway

From NICE NG62 Cerebral palsy in under 25s: assessment and management[6]

Managing saliva control

1.11.1 Assess factors that may affect drooling in children and young people with cerebral palsy, such as positioning, medication history, reflux and dental issues, before starting drug therapy.

1.11.2 **To reduce the severity and frequency of drooling in children and young people with cerebral palsy, consider the use of anticholinergic medication:**

- **glycopyrronium bromide (oral or by enteral tube) or**
- transdermal hyoscine hydrobromide **or**
- trihexyphenidyl hydrochloride for children with dyskinetic cerebral palsy, but only with input from specialist services.

When choosing which medicine to use, take into account the preferences of the child or young person and their parents or carers, and the age range and indication covered by the marketing authorisations.

1.11.3 Regularly review the effectiveness, tolerability and side effects of all drug treatments used for saliva control.

1.11.4 Refer the child or young person to a specialist service if the anticholinergic drug treatments outlined in recommendations 1.11.2 and 1.11.3 are contraindicated, not tolerated or not effective, to consider other treatments for saliva control.

1.11.5 Consider specialist assessment and use of botulinum toxin A injections to the salivary glands with ultrasound guidance to reduce the severity and frequency of drooling in children and young people with cerebral palsy if anticholinergic drugs provide insufficient benefit or are not tolerated.

1.11.6 Advise children and young people and their parents or carers that high-dose botulinum toxin A injection to the salivary glands can rarely cause swallowing difficulties, and so they should return to hospital immediately if breathing or swallowing difficulties occur.

1.11.7 Consider referring young people for a surgical opinion, after an assessment confirming clinically safe swallow, if there is:

- a potential need for lifelong drug treatment or
- insufficient benefit or non-tolerance of anticholinergic drugs and botulinum toxin A injections.

A range of other pharmacological options are available to treat hypersalivation. Most of them are antimuscarinic drugs and all are unlicensed in the UK for the treatment of hypersalivation. There are no randomised controlled comparative studies, so prescribers should consider evidence for effectiveness, potential side effects and available routes of administration when choosing between them. The absence of long-term studies means that there is no evidence for continued effectiveness or safety if used continuously for long periods.

Evidence review

NICE Evidence Summary (ES5) - Severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide
https://www.nice.org.uk/advice/es5/chapter/Key-points

As stated in summary above.

Current PCN Standard Operating Procedure for conducting evidence reviews states that if there is an up to date summary from a Trusted source e.g. NICE evidence summary, MTRAC, SMA, AWSMG, London Medicines Evaluation Network, then it is unnecessary to do an additional evidence review, and that NICE accredited guidelines should be given precedent over non NICE accredited guidance

Equity / Stakeholder views (if relevant)	
Decisions of local Trusts DTCs and neighbouring APCs	Brighton and Hove Clinical Commissioning Group, High Weald Lewes Havens Clinical Commissioning Group and Brighton and Sussex University Hospitals NHS Trust Joint Formulary: BLACK A3.13.12 Antiperspirants: Glycopyrronium bromide - all oral preparations Royal Cornwall Hospitals NHS Trust: (similar to Blue status) Referral criteria • Glycopyrrolate will be initiated by the consultant in patients with severe drooling who have tried other antimuscarinic treatments but have found these therapies inadequate or intolerable due to side effects. • 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. East London Foundation NHS Trust Unlicensed Medicines Policy 2007 Pirenzepine - Clozapine-induced hypersalivation East Kent Hospitals University Trust: Red – restricted Consultant Dermatologists. Unlicensed for hyperhidrosis and not prescribed for hypersalivation. NHS Crawley and NHS Horsham and Mid Sussex CCG Formulary http://www.chmsformulary.nhs.uk/chaptersSubDetails.asp?FormularySectionID=20&SubSectionRef=20&SubSectionID=A100#5247 – accessed 12 October 2016 Blue - Initiation : Specialist only, Repeat Prescribing : Primary care Monitoring : Primary care , Comment : Should be initiated by a specialist. Monitoring of either medicine or disease does not require specialist skills or equipment Off-label use in hypersalivation. Glycopyrronium should be used as a treatment option for patients who have tried other antimuscarinic treatments but have found these therapies inadequate or intolerable due to side effects.
Recommendations from national / regional decision making groups	**NICE NG62 Cerebral palsy in under 25s: assessment and management**[6] This guideline includes recommendations on: • causes and recognition of cerebral palsy • multidisciplinary care and information and support • managing feeding and drooling problems • support with speech, language and communication • assessing and managing pain, discomfort, distress and sleep disturbances • information on other comorbidities, including mental health problems • transition to adults' services And specifically mentions that the use of glycopyrronium should be considered to reduce the severity and frequency of drooling in children and young people with cerebral palsy.
Stakeholder views	No comments received from local stakeholders in response to consultation on this paper.
CCG priorities	• QIPP • Use of unlicensed medicines policy – preference to use a licensed drug for an unlicensed indication.

Health economic considerations	
Cost per year per patient	• Glycopyrronium bromide 400 microgram/ml oral solution (Sialanar) costs £320 per 250 ml bottle (MIMS, February 2017). At a dose of 1,600 micrograms (4 ml) three times daily the 28-day cost is £430.08 (based on a child weighing 33 kg at a dose of 48 micrograms/kg glycopyrronium bromide)[1]. • Once opened the bottle has a shelf life of 28 days. Any liquid remaining after this time should be discarded[1]. • The manufacturer estimates that there are approximately 1,500 children in England who may be eligible for treatment with glycopyrronium bromide[1].
Alternative	Costs of other treatments in comparison to Sialanar[1]

treatments cost per patient per year	

Medicine	Usual dose[a]	28-day cost (exc VAT)
Glycopyrronium bromide 400micrograms/ml oral solution (Sialanar)	1,600 micrograms (4ml) three times daily	£430.08[b]
Glycopyrronium bromide 1mg/5ml oral solution (Colonis)[c]	1mg (5ml) three times daily	£318.45[e]
Glycopyrronium bromide tablets 1mg or 2mg[c]	1-2mg three times daily	£635-711[e]
Hyoscine hydrobromide 150microgram tablets (Kwells Kids)[c]	150 micrograms three times daily	£11.69[d]
Hyoscine hydrobromide 1.5mg/72hrs patches (Scopadem)[c]	Apply every 72 hours	£23.19[d]

[a] doses shown do not represent the full range that can be used and do not imply therapeutic equivalence.
[b] Costs based on MIMS, February 2017; excluding VAT.
[c] Not licensed for the treatment of sialorrhoea; use would be off-label.
[d] Costs based on Drug Tariff, January 2017; excluding VAT
[e] Costs based on MIMS, March 2017; excluding VAT

Other financial considerations (if relevant)	
Health economic data (if available)	

1. NICE Evidence Summary ES5 – Severe sialorrhoea (drooling) in children and young people with chronic neurological disorders: oral glycopyrronium bromide
2. Ganesh Bavikatte, Poh Lin and Ali Hassoon. Management of Drooling of saliva. British Journal of Medical Practitioners. [Online]. 2012; 5(1):a507.Available at http://www.bjmp.org/content/management-drooling-saliva
3. Gastrointestinal system. In: Baxter K, BNF Director.British National Formulary. 68th ed. London: BMA & RPSGB; 2014. p.48 and 900 - 901.
4. Summary of Product Characteristics (Sialanar®)
5. NICE National Institute for Health and Care Excellence. ESUOM15: Hypersalivation: oral glycopyrronium bromide. [Online]. Available at: https://www.nice.org.uk/advice/esuom15
6. NICE Guidance NG62 Cerebral Palsy in under 25s: assessment and management

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