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Eye preparations

This bulletin considers the use of eye preparations in primary care, with a focus on those used for glaucoma and for managing dry eye disease. It offers guidance and support material for organisations considering reviewing these treatments.

In England, Wales, Northern Ireland, Isle of Man and Scotland approximately £137million is spent annually on the prescribing of branded glaucoma eye preparations and ocular lubricants including simple eye ointment (NHSBSA (Oct-Dec 2023) and Public Health Scotland (Aug-Oct 2023)).

Medicines optimisation projects can support quality improvement, value and sustainability in healthcare. For eye preparations such projects focus on appropriate treatment choices, effective use of products, minimisation of waste and the promotion of self care where appropriate.

For consideration of sustainability issues for eye preparations, refer to PrescQIPP bulletin 340. Sustainability in medicines optimisation.

Recommendations

Ocular hypertension (OHT) and chronic open angle glaucoma (COAG)

- Ophthalmologists should initially offer patients newly diagnosed with either OHT requiring treatment or COAG, 360° selective laser trabeculoplasty (SLT).
- Be aware that 360° SLT can delay the need for eye drops but does not remove the chance that they will be needed at a later date. A second 360° SLT may also be needed at a later date particularly if the effect on intraocular pressure (IOP) has reduced over time.
- Ophthalmologists should offer a generic prostaglandin analogue (PGA) eye drop to people if:
  - They choose not to have 360° SLT or it is not suitable for them,
  - They are waiting for 360° SLT and need an interim treatment, or are awaiting glaucoma surgery for advanced COAG, or
  - They have had 360° SLT but need additional treatment.
- If a second line pharmacological treatment is needed (due to tolerability issues or insufficient effect) ophthalmologists may offer alternative generic PGA, a topical beta-blocker, a non-generic PGA, a topical sympathomimetic, a topical carbonic anhydrase inhibitor, a topical miotic or a combination of treatments. Topical medicines from different therapeutic classes may be needed at the same time to control IOP.
- Offer preservative-free preparations to people with COAG (or OHT with a high risk of conversion to COAG) if they have an allergy to preservatives or clinically significant ocular surface disease.
- Demonstrate correct eye drop installation technique and observe the person using the correct technique when eye drops are first prescribed.
- Ask about adherence and support people to overcome any barriers. Be vigilant for issues due to differences in generic eye drop bottles, such as altered appearance causing confusion or incompatibility with an administration aid.

Recommendations

Dry eye disease

- In accordance with NHS England guidance, do not routinely offer a prescription for ocular lubricants for cases of mild to moderate dry eye disease. Advise people how to self care with lifestyle modifications (including warm compresses and lid hygiene) and purchased over the counter (OTC) ocular lubricants, if needed. Guidance across the UK varies (see 'Self care with OTC products' section).
- Consider auditing ocular lubricant prescribing to identify patients that may be suitable for self care OTC. Patients to prioritise for review include:
  - Those without a diagnosis of dry eye disease, and
  - Those whose eye lubricants are issued irregularly.
- Consider if systemic medication could be contributing to dry eye symptoms. Where clinically appropriate consider a dose reduction, different route of administration, or switching to alternative treatment(s).
- Include a range of cost-effective first and second line ocular lubricant options in local formulary guidance.
- In general, start with a less viscous ocular lubricant as these are less likely to cause stinging and blurring. Consider factors that may be important for the individual e.g. ease of use for people with dexterity issues.
- Refer the person to ophthalmology or an appropriate specialist if they have persistent or severe symptoms that do not respond to primary care management after 4–12 weeks, depending on clinical judgement.
- Advise on the use of preservative-free eye preparations for dry eye disease, particularly for those who are intolerant of preservatives, require topical preparations more than four times per day, use multiple preparations or who use soft or hybrid contact lenses.

Background

There are several methods of achieving therapeutic drug concentrations within the eye and its surrounding structures. By far the most common is topical administration, using eye drops or ointments.[1] Most eye preparations used therapeutically in primary care fall into one of the following categories:

- Glaucoma treatments.
- Dry eye disease treatments.
- Anti-infectives.
- Corticosteroids and other anti-inflammatories.
- Antihistamines.

Ocular anti-infectives should be used in accordance with local antimicrobial guidance. Chloramphenicol eye preparations can be purchased OTC for the treatment of acute bacterial conjunctivitis in adults and children aged over two years.[2]

Corticosteroids administered locally to the eye or given by mouth are effective for treating anterior segment inflammation, including that which results from surgery.[2] Treatment with corticosteroid eye preparations should always be initiated in secondary care by a specialist, as there are potential complications with their use. However, treatment may be continued and monitored in primary care following a specialist management plan.[3]

Eye drops containing antihistamines and mast cell stabilisers are used in managing allergic conjunctivitis, including that caused by seasonal allergens such as pollen.[4] Some, such as sodium cromoglicate, can be purchased OTC.[2]

Glaucoma treatments and dry eye disease treatments are considered in more detail below.

Glaucoma

Glaucoma describes a group of eye disorders characterised by a loss of visual field associated with pathological cupping of the optic disc and optic nerve damage. While glaucoma is generally linked to raised IOP, which is the main treatable risk factor, it can also occur when the IOP is within the normal range. Other risk factors include age, family history, ethnicity, corticosteroid use, myopia, type 2 diabetes mellitus, cardiovascular disease, and hypertension.[2]

The most common form of glaucoma is chronic (or primary) open angle glaucoma (COAG or POAG), which accounts for over 70% of all glaucoma cases.[5] Drainage of the eye's aqueous humour through the trabecular meshwork is restricted, and the angle between the iris and the cornea is normal. Initially, this condition tends to be asymptomatic, however, as glaucoma progresses, patients may present with irreversible sight loss or visual field defects.[2]

OHT describes elevated IOP (OHT is IOP greater than 21 mmHg) in the absence of optic nerve damage or visual field loss. It can be present for many years without the development of glaucoma, however sustained elevation of IOP causes damage to the optic nerve head and is a major risk factor for the development of glaucoma. Lowering OHT has been shown to lower the risk of developing glaucoma.[5]

COAG has an estimated UK prevalence of 2% of people over the age of 40. The overall risk of developing COAG increases substantially with increasing IOP and age. OHT is estimated to affect 3-5% of people over the age of 40, although not all will need treatment.[5]

Treatment of all types of glaucoma, and of OHT when indicated, is normally initiated and monitored by specialists. The mainstay of treatment is to reduce IOP to avoid visual loss or impairment. Treatment may take the form of laser procedures, eye drops or surgical procedures.[6]

Eye preparations recommended by the specialist are often prescribed and supplied in primary care. Primary care practitioners therefore have an important role in providing appropriate glaucoma medicines (and information about them), monitoring for allergy and other adverse effects, promoting correct use and supporting adherence.[6]

National Guidance

In January 2022 NICE published an update to their guidance on the diagnosis and management of glaucoma (NG81).[7] They reviewed the evidence and updated the recommendations on treatment for OHT and COAG.

The guidance recommends that people with OHT who are not at risk of visual impairment within their lifetime should not be offered treatment. Those with suspected COAG and IOP less than 24 mmHg should also not be offered treatment unless they are at risk of visual impairment within their lifetime. In both cases people should be advised to continue regular visits to their primary eye care professional.[7]

Treatment should be offered to people with:

- COAG
- OHT and an IOP of 24 mmHg or more if the person is at risk of visual impairment within their lifetime.

A significant change in this latest update is that NICE now recommend that people newly diagnosed with either OHT requiring treatment or COAG should initially be offered 360° SLT.[7] Previous guidance recommended IOP-lowering eye drops first-line.[8]

360° SLT is a procedure that involves a low-energy laser being fired at the trabecular meshwork to improve drainage and reduce IOP.[6] It is performed as an outpatient procedure.[9] It is not a suitable treatment for cases associated with pigment dispersion syndrome, where eye drops should be used first-line.[7]

360° SLT can delay the need for eye drops but does not remove the chance that they will be needed at a later date. A second 360° SLT may also be needed at a later date particularly if the effect on IOP has reduced over time.[7]

Eye drops still have a significant role in managing COAG and OHT for many people. A generic PGA eye drop should be offered to people if:

- They choose not to have 360° SLT.
- 360° SLT is not suitable.
- They are waiting for 360° SLT and need an interim treatment.
- They have had 360° SLT but need additional treatment to reduce their IOP sufficiently to prevent the risk of visual impairment.[7]

Topical PGAs such as latanoprost, tafluprost, travoprost, or bimatoprost (a synthetic prostamide) reduce IOP by enhancing uveoscleral outflow of aqueous humour and may also increase the trabecular meshwork outflow.[6]

People with advanced COAG should be offered a generic PGA while waiting for glaucoma surgery.[7]

The guideline does not suggest that patients currently well managed with eye drops need to have their treatment changed. It does allow for 360° SLT to be considered where there are problems with current treatment such as insufficient control of the condition or adverse effects.[7]

NICE specify that people should be shown how to administer eye drops and observed using them when they are first prescribed. If IOP has not been reduced sufficiently despite pharmacological treatment with a generic PGA, people should be asked about adherence and have their eye drop instillation technique checked.[7]

If a first-line pharmacological treatment is unsuccessful, or not tolerated, second-line treatment options that may be considered by the ophthalmologist include:

- Switching to an alternative generic PGA.
- A topical beta-blocker.
- Switching to, or adding in, a second-line drug treatment, which are: a non-generic PGA, a topical sympathomimetic, a topical carbonic anhydrase inhibitor, a topical miotic or a combination of treatments.

Preservative-free preparations can be offered to people with COAG if they have an allergy to preservatives or clinically significant ocular surface disease. In those without a diagnosis of COAG, preservative-free preparations should only be considered where the risk of conversion to COAG is high. This is on the grounds of cost-effectiveness.[10]

Before offering pharmacological treatment, checks for relevant co-morbidities or potential drug interactions should be made.[7]

Reassessment frequency depends on factors such as whether IOP is controlled and whether the condition appears to be progressing (e.g. if there are signs of OHT or suspected COAG converting to COAG, or if there are signs of COAG progression). Those at a higher risk need more frequent monitoring.[7]

NICE have published visual summaries of the management options for people with OHT and people with COAG.

NHS England have published a decision support tool for patients: Making a decision about open-angle glaucoma.

A new eye drop containing netarsudil mesylate and latanoprost (Roclanda®) was launched in the UK in 2023. Netarsudil, a new molecule for glaucoma, is a Rho kinase inhibitor that works on the trabecular meshwork of the eye.[11] Roclanda® has a marketing authorisation for the reduction of elevated IOP in adult patients with POAG or OHT for whom monotherapy with a prostaglandin or netarsudil provides insufficient IOP reduction. NICE are developing a technology appraisal on netarsudil-latanoprost for previously treated COAG or OH.[12]

Guidelines from the Scottish Intercollegiate Guidelines Centre (SIGN) are available on referral and safe discharge for people with glaucoma (SIGN 144, published in 2015). It focuses on primary-care assessment and referral of patients with suspected glaucoma, of any subtype, from the community into secondary eye-care services and the safe discharge of patients from secondary eye-care services back into the community. The guideline excludes treatment of OHT and COAG, as they are covered by NICE Guidance.[13]

Clinical and cost effectiveness

NICE undertook a review to compare the effectiveness and cost-effectiveness as a first line treatment of 360° SLT and IOP-lowering eye drops in OHT or COAG in adults. Five randomised controlled trials (RCTs) were included, the largest and most recent being a 2019 UK study called the LiGHT trial by Gazzard et al.[9]

Evidence was mainly identified for newly diagnosed OHT or newly diagnosed COAG. People with secondary glaucoma associated with pigment dispersion syndrome were excluded from the LiGHT trial, resulting in the recommendation to use eye drops first-line in such cases.[9]

High quality evidence showed that there was no meaningful difference between 360° SLT and eye drops in achieving the target IOP, no meaningful difference in the change of health-related quality of life overtime, no meaningful difference in the risk of total adverse events, and no meaningful difference in treatment adherence.[9]

For the economic analysis, NICE included two studies from the existing literature, both reporting different results from the LiGHT trial.[9] Both studies found 360° SLT to dominate (cost less and provide more QALYs than) first-line treatment with eye drops. The lower costs of 360° SLT were primarily driven by the need to use significantly fewer eye drops, which reduces costs both of the medicines themselves, and also appointments to monitor and modify treatment.

The NICE committee recognised that older people, including people with cognitive or physical impairment (e.g. arthritis), people with learning disabilities and people with dementia might find it difficult to administer eye drops or may require assistance from carers in receiving IOP-lowering eye drops to manage their OHT or COAG. They also note that IOP-lowering eye drops might not be the preferred treatment during pregnancy or breastfeeding because of potential side effects (manufacturers advise to avoid use during pregnancy and breastfeeding). The new recommendations allow 360° SLT to be considered as a treatment option in these groups.[9]

NICE did not update their evidence review on choice of pharmacological treatment. Where eye drops are indicated the hierarchy of options remains unchanged from the 2017 version of NG81, with a generic PGA being the first-line choice. PGAs are the most clinically effective first-line pharmacological and they are associated with less adverse effects compared with other treatments. Generic PGAs are specifically recommended as they were shown to be the most cost-effective pharmacological treatment for lowering IOP.[10]

Prescribing considerations

Generic prescribing

A number of eye drops used in the treatment of glaucoma are available as generic products, including several PGAs/synthetic prostamide.[2] Generic latanoprost was introduced in 2012, followed by generic bimatoprost and travoprost. There is a significant price difference between the branded and generic products[14] which represents considerable savings for the NHS if the generic versions are preferentially prescribed.

The Royal College of Ophthalmologists advocate that commissioners recommend the use of generic medication where appropriate, given the potential cost savings. However, commissioners should be aware that:

- If a patient with stable glaucoma is tolerating a branded medication well, it may not be appropriate or cost-effective to switch to a generic version of that medication.
- The different appearance of the bottle may cause confusion, especially with the visually impaired, and the bottle may not be as easy for the patient to use.
- Switching to a generic medication may prompt extra monitoring visits – there will be costs associated with this.
- Patients should receive instruction on the correct use of eye drop administration aids.
- Patients may need different eye drop administration aids if their drops are changed because generic bottles are not necessarily the same size, rigidity nor shape and may not fit their present aid.
- Any adverse events observed on a switch to a generic medication should be reported through the yellow card system.[15]

It should be noted that Xalatan® was reformulated in 2013, reducing the pH from 6.7 to 6.0, to allow for long term storage at room temperature. Following this reformulation there was an increase in the number of reports of eye irritation with the product across Europe. It is important that patients continue their treatment. Therefore advise patients to tell their health professional promptly (within a week) if they have eye irritation (e.g. excessive watering) severe enough to make them consider stopping treatment. Review treatment and prescribe a different formulation if necessary.[16]

Generic prescribing of PGAs/synthetic prostamide is now well established in the NHS, with 82% of prescriptions for latanoprost, travoprost and bimatoprost being generic. The remaining prescriptions are for branded generics (10%) and for the originator brands (8%).[17] Such trends are consistent with NICE guidance, which recommends generic PGAs as first-line pharmacological treatment, but allows for non-generic PGAs in some circumstances. The recent changes to NICE guidance advocating wider use of 360°SLT may reduce the need for non-generic eye drops further.[7]

Local decisions regarding the use of generic glaucoma eye preparations should be made in collaboration with local ophthalmologists. Areas that recommend generic prescribing of glaucoma eye preparations can support primary care prescribers by ensuring that clinic letters from ophthalmologists use generic names (unless a branded product is specifically recommended). Local initiatives to promote generic prescribing should include checks to ensure that patients with a clinical need for a branded product do not have their medication changed inadvertently. Attachment 1 lists the brand and generic names of glaucoma eye drops.

Be aware that in some instances generic prescribing could increase the risk of medication errors due to similar sounding or similar looking product names. An example involving eye preparations is brimonidine and brinzolamide drops. Particular care must be taken when prescribing or dispensing these products. Similar problems are possible with certain brand names, e.g. Xalatan® and Xalacom®, Cosopt® and Trusopt®. A quick reference guide to brand and generic names of glaucoma eye drops is available in attachment 1 accompanying this bulletin.

Fixed combinations

The need for multiple eye drops may adversely affect adherence, increase exposure to preservatives[18] and if done incorrectly could reduce efficacy through wash-out of the earlier drop with the latter drop.[19] Use of a fixed combination drop can avoid these issues.[18]

However, fixed combinations remove the possibility of titrating the individual components both in terms of concentration and timing of administration. Most of the fixed-dose combinations available in the UK contain timolol 0.5% (the exceptions being brinzolamide/brimonidine – Simbrinza® and latanoprost/netarsudil – Roclanda®). Beta-blockers are contraindicated in some people due to the risk of systemic side-effects. Furthermore, unnecessary side-effects may arise as a result of the higher concentration of timolol (0.5%) in all currently available fixed combinations.[10] Some (but not all) fixed combinations also currently cost more to prescribe than their separate constituents.[14,20] Refer to the PrescQIPP cost comparison charts.

Adherence

Adherence and persistence with the prescribed glaucoma management is necessary to obtain IOP-lowering and to prevent glaucoma progression.[18] Problems with adherence to treatment are well recognised in glaucoma, which is asymptomatic in its early stages.[15]

NICE recommend asking about general health and, if appropriate, factors affecting adherence to treatment, including cognitive impairment and any treatment side effects at each assessment.[7]

European guidance discusses ways to detect non-adherence. An empathetic approach is recommended with the use of open-ended questions, e.g.

- Have you forgotten to use your eye drops during the last week? If yes, how many times?
- Do you have any concerns or difficulties with your eye drops?

Where a person instils their own drops, asking them to demonstrate their technique can be useful.[18]

Current evidence does not support any specific interventions to improve adherence, but identifies that patient education including behaviour change techniques, and simpler medication dosing regimens may be effective. Patient education is more effective at changing behaviour if it includes teaching people how to instil eye drops, identification of barriers to drop instillation, a review of the person's beliefs about medication and an agreed personal plan of action on how to improve adherence.[15]

Patient information resources are available from:

- The Glaucoma UK website, which has a range of resources including:
  - Information about eye drops and how to instil them https://glaucoma.uk/about-glaucoma/treatments-surgery/eye-drops/
  - Eye drop dispensing aids https://glaucoma.uk/about-glaucoma/treatments-surgery/about-glaucoma-treatments-surgery-eye-drop-dispensing-aids/
- The Moorfields Eye Hospital website has a short video for tips on how to correctly administer eye drops. https://www.moorfields.nhs.uk/for-patients/pharmacy#meds Moorfields also have a range of patient information leaflets available explaining how to use a variety compliance aids to help with stabilising the bottle over the eye so that a drop can be accurately squeezed into the eye. https://www.moorfields.nhs.uk/for-health-professionals/leaflet-library

Prostaglandin analogues (latanoprost, tafluprost, travoprost) and synthetic prostamides (bimatoprost) can cause eye colour changes. Before initiation, people should be warned that an increase in the brown pigment in the iris can occur, which may be permanent; particular care is required in those with mixed coloured irises and those receiving treatment to one eye only. Changes in eyelashes and vellus hair (fine short hair on the body) in the treated eye and surrounding areas can also occur. Repeated contact of the eye drop solution with skin should be avoided as this can lead to hair growth or skin pigmentation.[2,21]

Reminder strategies that some people may find helpful are: keeping in-use eye drops next to their toothbrush (so that they are reminded to use them when they brush their teeth), setting an alert on their phone or ticking off a days of the week chart when they have instilled their drops. A drop chart can be downloaded from the Glaucoma UK website at https://glaucoma.uk/wp-content/uploads/2020/06/Drop_Calender_2016.pdf.[22] Patients could also consider using a medication reminder app on their smartphone.

For patients with difficulties in administering their eye drops, consider an eye drop dispensing aid. These may be particularly useful for older people or those who are visually impaired, have arthritis or are otherwise physically limited. If dexterity is an issue, individual consultation with the patient about use should be considered.[23] The following are available on prescription:[20]

- Opticare® - Positions over the eye for accurate application and makes it easier to squeeze the bottle.
- Opticare® Arthro – Ideal for those with severe arthritis or limited hand or shoulder movement.
- ComplEye® - For use with Hylo-Tears® and Hylo-Forte® bottles. Positions over the eye for accurate application of drops.[24]
- eyGuide® – for use with multi-dose preservative free bottles.[25]

Dry eye disease

Dry eye disease (or 'dry eye syndrome' or 'keratoconjunctivitis sicca') is a multifactorial disease of the ocular surface characterized by a loss of homeostasis of the tear film with reduced tear production or tear film instability, associated with ocular discomfort and/or visual symptoms.[26]

It is a common, chronic condition that occurs more commonly in women and with increasing age.[26,27] It is categorised based on its pathophysiology into two groups that often overlap and co-exist:

- Evaporative dry eye - the most common form of dry eye syndrome, often associated with increased tear film evaporation. This is most often due to dysfunction of the meibomian glands, which produce the lipid component of tears.[26]
- Aqueous deficient dry eye - reduced aqueous secretion from lacrimal glands causing a reduced tear volume.[26] It can be associated with non-autoimmune causes (including some medications such as antihistamines), as well as autoimmune diseases such as rheumatoid arthritis, Sjögren's syndrome and systemic lupus erythematosus.[23]

In the majority of cases, dry eye disease can be managed with appropriate patient self-management and pharmacological treatment options, which are usually first-line ocular lubricants in primary care.[23]

National guidance

NICE has not issued guidance on the management of dry eye syndrome, but they have published a Technology Appraisal on ciclosporin eye drops for treating dry eye disease that has not improved despite treatment with artificial tears.[28]

The All Wales Medicines Strategy Group (AWMSG) issued Dry Eye Syndrome Guidance in 2016. It includes advice on self management, pharmacological management (first-/second- line treatment options and preservative toxicity) and referral.[23]

Guidance called the Dry Eye Workshop II (DEWS II) is available from the Tear Film & Ocular Surface Society.[29]

A Clinical Knowledge Summary is available for dry eye disease, which takes the DEWS II guidance into consideration.[26] It recommends referring people with symptoms of dry eye disease in the following circumstances:

- Urgent ophthalmology same-day assessment if the person has:
  - Red flag symptoms or signs which may indicate a serious or sight-threatening cause e.g. sudden-onset pain or visual loss, persistent or severe visual loss, diplopia, unilateral symptoms, or systemic symptoms such as weight loss or fever.
  - A suspected serious complication e.g. damage to the corneal epithelium, corneal infection.
- Urgent referral to ophthalmology if a serious underlying cause is suspected e.g. Stevens-Johnson syndrome.
- Referral to ophthalmology or an appropriate specialist, the urgency depending on clinical judgement, in the case of:
  - Uncertain diagnosis, especially if a child has unexplained symptoms or suspected corneal changes.
  - Suspected underlying systemic condition e.g. Sjögren's syndrome.
  - Abnormal lid anatomy or function.
  - Persistent or severe symptoms that do not respond to primary care management after 4–12 weeks, depending on clinical judgement.

For patients that do not need urgent specialist referral and can be managed in primary care the CKS recommends advising on lifestyle measures for symptom relief, such as:

- Warm compresses, lid hygiene, and lid massage, especially if blepharitis or meibomian gland dysfunction are present.[26] Eyelid hygiene involves cleansing the eye lid using diluted 1:10 baby shampoo, a solution of sodium bicarbonate in warm water, or manufactured lid cleansing products,[30] all of which can be purchased. Various patient information resources describing self care for blepharitis are available (see 'Patient information resources' section on page 13).
- Modification of contact lens wear.
  - Wearing contact lenses for shorter periods, and remove lenses if dry eye symptoms occur.
  - Changing lens type or solution may help (ask optometrist).
- Moisture chamber eyewear (such as wrap-around glasses or specialist goggles).
- Modification of environmental factors including -
  - Increase relative humidity and avoid prolonged periods of digital device use or exposure to air conditioning or drafts, if possible.
  - Lower computer screens to below eye level (decreasing lid aperture), and increase blink frequency with digital device use and reading.
  - Avoid alcohol and exposure to cigarette and other smoke.[26]

Certain systemic drugs can contribute to dry eye disease symptoms, including:

- Anticholinergics
- Antihistamines
- Antipsychotics
- Anxiolytics
- Beta-blockers
- Diuretics
- Isotretinoin
- Oral contraceptives or hormone replacement therapy containing oestrogen
- Tricyclic antidepressants[26]

Where clinically appropriate consider a dose reduction, different route of administration, or switching to alternative treatment(s).[26]

If lifestyle measures are insufficient for symptom relief, patients should be advised on the use of ocular lubricants ('artificial tears').[26] Although there are numerous formulations and products available, there does not appear to be any substantial difference in effectiveness among them.[29] A wide range of ocular lubricants are available to purchase OTC.[26]

Low-viscosity drops such as hypromellose are usually recommended for daytime use due to the reduced risk of adverse effects such as blurred vision, eyelid debris, and eye stinging. Increased viscosity ointments or gels may be needed for overnight use.[26]

Both the BNF and the AWMSG advise that hypromellose should be appropriate for the majority of patients presenting with mild dry eye syndrome. Carbomers* and polyvinyl alcohol are suggested as alternative first line options.[2,23] They require less frequent administration but may be less well tolerated than hypromellose.[23]

If symptoms are not relieved with an initial topical preparation after four to six weeks, a second line ocular lubricant may be considered.[26] This could be a product containing hydroxypropyl guar, carmellose sodium or sodium hyaluronate.[23] If symptoms do not respond to primary care treatment after four to twelve weeks, arrange specialist referral, depending on clinical judgement.[26]

Encourage adherence to eye drops and the use of warm compresses if there is evidence of meibomian gland dysfunction. Be aware that adherence to the use of warm compresses is thought to be poor.[31]

Specialists may consider other treatments including acetylcysteine eye drops or ciclosporin eye drops.[23] NICE recommend ciclosporin eye drops as an option for treating severe keratitis in adults with dry eye disease that has not improved despite treatment with tear substitutes.[28]

* For carbomers, be aware of safety advice issued by the Medicines and Healthcare products Regulatory Agency in November 2023 regarding potential microbial contamination. Patients and healthcare professionals should stop using the specified batches of the brands named in the recall. Furthermore, as a precautionary measure, *all carbomer eye gels* should be avoided in individuals with cystic fibrosis, patients being cared for in critical care settings (e.g. intensive care), or who are severely immunocompromised and in hospital, and for patients awaiting lung transplantation.[32]

Simple eye ointment contains liquid paraffin, wool fat and yellow soft paraffin and is indicated for eye surface lubrication in children and adults.[2] Simple eye ointment's cost is disproportionately expensive compare to alternative ocular lubricants, refer to the PrescQIPP cost comparison charts for ocular lubricants.

Self care with OTC products

Guidance from NHS England states that mild to moderate cases of dry eye disease or sore tired eyes can usually be treated using lubricant eye treatments that can easily be purchased OTC. They advise that a prescription for treatment of dry or sore eyes should not routinely be offered in primary care as the condition is appropriate for self care.[33]

NHS England's guidance is intended to encourage people to self-care for minor illnesses as the first stage of treatment. If symptoms are not improving or responding to treatment, patients should be encouraged to seek further advice.[33]

Patients will need to be provided with better information on signposting so that they are able to access the right service, including the GP when appropriate.[33] A patient information leaflet explaining the changes to the prescribing of OTC medicines is available, and further resources about dry eye disease and blepharitis can be found in the 'Patient information resources' section on page 13.

NHS England outline a number exceptions to their guidance, where patients should continue to have their treatments prescribed for:

- Managing a long-term condition (for example, regular pain relief for chronic arthritis or treatments for inflammatory bowel disease).
- Treating more complex forms of minor illnesses (for example, severe migraines that are unresponsive to OTC medicines).
- Managing presentations of symptoms that suggest the condition is not minor.
- 'Red flag' symptoms (for example, indigestion with very bad pain).
- Patients with complex conditions (for example, immunosuppressed patients).
- Treating an adverse effect or symptom of a more complex illness.
- Treating a minor condition suitable for self-care that has not responded sufficiently to an OTC item.
- Circumstances where the prescriber's clinical judgement is that these are exceptional and warrant deviation from the recommendation to use self-care.
- Individual patients where the prescriber considers that the patient's ability to self-care is compromised because of medical, mental health or significant social vulnerability to the extent that their health and/or wellbeing could be adversely affected if reliant on self-care.
- Circumstances where the product licence does not allow the item to be sold OTC to certain groups of patients. These may vary by medicine, but could include babies, children and/or women who are pregnant or breastfeeding. Community pharmacists will be aware of what these are and can advise accordingly.[33]

Each individual's clinical circumstances need to be considered in light of the guidance. Examples of scenarios where eye lubricant prescribing would be appropriate include the treatment of severe dry eye disease, or where dry eye is a symptom of a more complex illness e.g. rheumatoid arthritis, Sjögren's syndrome and systemic lupus erythematosus.

Where no underlying condition or red flags are identified and the symptoms are mild or moderate, it may be useful to establish whether the patient is using eye lubricants everyday or occasionally/ periodically, and why. Discuss self-care measures and avoidance of environmental factors with the patient.. Medicines management teams should consider discussing continued dry eye treatment with local secondary care specialists to agree a coordinated local approach to when prescribing or OTC purchase is recommended.

All patients should be advised that if their symptoms do not respond after four to twelve weeks they should make an appointment with their GP, who may arrange referral to a specialist, depending on their clinical judgement.[26]

A proposal for similar guidance in NHS Wales was rejected by the AWMSG.[34]

In NHS Scotland, a number of ocular lubricants are included in the list of approved medicines for the Pharmacy First Scotland scheme.[35]

Northern Ireland formulary guidance advises prescribers that simple dry eye can be managed by providing a patient information leaflet on dry eye, directing the patient to self care and to purchase dry eye lubricants OTC.[36] Patient information leaflets on dry eye disease and blepharitis can be found within the Northern Ireland formulary.

Clinical effectiveness

A Cochrane review investigated the effect of OTC tear supplement products for treating dry eye disease. It included 43 RCTs (n=3497) that had compared artificial tear formulations to each other,

placebo, or no treatment. The primary outcome measure was patient-reported symptoms. Overall, the quality of evidence was assessed as low. The authors concluded that OTC artificial tears may be safe and effective for treating dry eye disease, with the literature indicating that the majority may have similar efficacies. However there is still a need for future research to draw robust conclusions about the effectiveness of individual OTC artificial tear formulations.[37]

Choice of ocular lubricant

It is logical to start with a less viscous formulation at first as these are less likely to cause stinging and blurring. Starting with the lowest cost preparations is also rational, whilst taking into consideration any factors that may be important for the individual e.g. ease of use for people with arthritis.[27]

Local guidance should support clinicians in recommending self care for appropriate patients and in promoting logical treatment options for different dry eye disease severities. It can also guide the selection of cost effective options for when prescribing is appropriate. Examples of local guidance include the Pan-London Dry Eye Guide and prescribing guidelines from Herefordshire and Worcestershire ICS.

Where prescribing is warranted, it is usually more appropriate for ocular lubricants to be prescribed by brand. This is because the majority of these products are classed as medical devices, rather than licenced medicines. If a prescription for an ocular lubricant that is a medical device is written generically, the price charged will be determined by which brand is dispensed,[38] which can result in unexpectedly high costs to the NHS. Only brands listed in the appliances section of the Drug Tariff can be prescribed.[20,38]

Those developing local guidance should consider including a range of cost-effective first and second line options to cater to different needs, and to ensure that alternatives can be easily selected if a formulary brand is out of stock. Cost comparison charts for eye preparations for dry eye disease are available at https://www.prescqipp.info/our-resources/data-and-analysis/financial-reports/cost-comparison-charts/. Subscribers to MIMS can access their table on dry eye treatments which lists the presentations and prices of ocular lubricants.

Excipients

Multidose ocular lubricants typically require a preservative to prevent microbial growth, whereas unit dose vials that are discarded after a single use do not. However, unit dose vials are more expensive, may be more difficult for less dextrous individuals to use and increase the plastic waste associated with treatment. A number of new products are now available that utilise dispensers that incorporate unidirectional valves that allow multidose bottles to be unpreserved.[29]

Compared to preparations containing a preservative, unpreserved eye preparations may have a shorter period of safe use. Consult the product packaging and see guidance on the in-use shelf life for eye drops and ointments for more information.[2]

The preservative benzalkonium chloride is frequently used in eye drop preparations. The DEWS II guidance states that sufficient evidence exists to confirm that patients with dry eye disease (particularly when it is severe) who require frequent dosing with lubricants or who use them in conjunction with other chronic topical therapies (e.g. for glaucoma) should avoid the use of ocular lubricants preserved with benzalkonium chloride.[29]

Newer variants of preservatives designed to have a lower impact on the ocular surface have also been developed e.g. sodium chlorite, which degrades to chloride ions and water upon exposure to UV light after instillation. Some reports suggest that even these so-called “disappearing preservatives” can show some negative effects on the ocular surface. Therefore, preservative-free drops may be a better choice for patients who have pre-existing ocular surface conditions and/or need frequent instillation of eye drops.[29]

Details of excipients (including preservatives) contained in eye preparations can be found in the Summary of Product Characteristics (SPCs) of individual products (usually available via https://www.medicines.org.uk/emc). The BNF lists preservatives and substances identified as skin sensitisers under excipients statements in preparation entries. Subscribers to MIMS can access tables on 'Ophthalmic Preparations, Preservatives and Potential Sensitisers as Ingredients'.

For those using multiple preserved topical medications, strategies such as using fixed-dose combinations in glaucoma (to reduce the preservative burden) or using products with preservatives other than benzalkonium chloride can be considered. For those with dry eye disease needing more than four instillations per day on a prolonged basis, a more viscous preparation could be considered to reduce the frequency of administration. However, for some people preservative-free products will be needed.

For dry eye disease, CKS advises considering preservative-free topical formulations, particularly if the person:

- Is intolerant of preservative in tear supplements (risk of conjunctivitis medicamentosa).
- Has moderate-to-severe dry eye disease requiring topical preparations more than four times per day.
- Is using multiple topical eye preparations.
- Uses soft or hybrid contact lenses.[26]

In 2012 the European Medicines Agency completed an assessment of the use of phosphate buffers in medicinal products given as eye drops and whether these can cause corneal calcification (build-up of calcium deposits in the cornea, the clear layer at the front of the eye). They considered that the benefits of phosphate-containing eye drops outweigh their risks but that in very rare cases patients with significant damage to the cornea may develop corneal calcification during treatment with eye drops that contain phosphate, and that this should be mentioned in the product information.[39]

Patient information resources

- The joint Royal College of Ophthalmologists and Royal National Institute of Blind People (RNIB) publication Understanding Dry Eye, which includes information on blepharitis.
- The patient.info leaflet on Dry eyes
- The patient.info leaflet on Blepharitis
- The NHS information on Dry eyes
- The NHS information on Blepharitis

Unlicensed 'specials'

Where a product is not available as a licensed medicine or a medical device, an unlicensed 'special' might be considered. The Royal College of Ophthalmologists and the UK Ophthalmic Pharmacy Group have issued clinical guidance on ophthalmic special order products (the document is updated periodically so check for most recent version at www.rcophth.ac.uk). The guidance addresses the potential uses of certain unlicensed ophthalmic preparations and suggests alternatives where appropriate. It also classifies products according to whether they are suitable for initiating and/or prescribing in primary or secondary care. The guidance includes the following recommendations:

- When clinically appropriate and available, licensed products should always be prescribed and dispensed in preference to unlicensed products.
- Where a licensed product is not available, specials products listed on the Drug Tariff for England and Wales part VIIIB (Scotland part 7S) or devices listed on the Drugs Tariff for England and Wales part IXA (Scotland part 3, N Ireland part III) are preferred.

- Excipient intolerances should be included on the prescription. Some licensed and unlicensed products, including those labelled preservative-free, contain potentially sensitising excipients (chelating agents such as EDTA).
- All ophthalmic preparations, whether preserved or preservative-free, should only be used for a limited period once opened. Justified and validated in-use shelf lives should be provided by the manufacturer.
- For items not on the list, please confirm with secondary care to ensure that a transcription error has not occurred.
- All ophthalmic specials should be initiated in specialist ophthalmic secondary care only and only prescribed in primary care according to secondary care instructions with secondary care supervision (where appropriate), unless otherwise indicated in the guideline.[40]

Costs

Cost comparison charts for both glaucoma eye drops and for dry eye disease preparations are available in the data pack accompanying this resource. They are also available on the PrescQIPP website where they are updated monthly at https://www.prescqipp.info/our-resources/data-and-analysis/financial-reports/cost-comparison-charts/ (login required).

Prescribing review and potential savings

In England, Wales, Northern Ireland, Isle of Man and Scotland approximately £137million is spent annually on the prescribing of branded glaucoma eye preparations and ocular lubricants including simple eye ointment (NHSBSA (Oct-Dec 2023) and Public Health Scotland (Aug-Oct 2023)). The breakdown of totals by country is provided in table 1.

Table 1. Branded glaucoma eye preparations, ocular lubricants and simple eye ointment spend by country (NHSBSA (Oct-Dec 2023) and Public Health Scotland (Aug-Oct 2023)

	Branded glaucoma preparations annual spend	Occular lubricants annual spend	Simple eye ointment annual spend
England	£29,053,896	£83,309,380	£613,348
Scotland	£4,021,164	£8,834,164	£24,524
Wales	£2,262,540	£6,027,308	£19,596
Northern Ireland	£750,940	£2,544,608	£6,572
Isle of Man	£93,404	£92,852	£780
Total	**£36,181,944**	**£100,808,312**	**£664,820**

Savings can be made by ensuring appropriate, cost effective product choices are made.

For dry eye disease, it is possible to identify patients suitable for self care by auditing ocular lubricant prescribing. Patients to prioritise for review include:

- Those prescribed ocular lubricants without a diagnosis of dry eye disease and
- Those whose ocular lubricants are issued irregularly (e.g. < 12 issues/year for monthly prescribing or <6 issues/year for two monthly prescribing).

Wastage may be reduced by ensuring patients generally have just one type of ocular lubricant. However, be aware that some patients require a lower viscosity product in the day and a higher viscosity product at night.

Simple eye ointment is currently disproportionately costly (£72.27 per 4g pack),[20] so consider suitable alternatives where possible.

It is recognised that some integrated care boards (ICBs) have already done significant work in this area and further cost savings may be limited. Individual ICBs can compare elements of their eye preparation prescribing to the national average using the 'Look, Review, Do' infographics included in the visual data pack as part of these resources.

In England, Wales, Northern Ireland, Isle of Man and Scotland a reduction in the prescribing of:

- **Branded glaucoma preparations by 20% (by prescribing generics instead) would produce savings in the order of £7.2million. This equates to £9,722 per 100,000 population.**
- **Ocular lubricants by 20% (by promoting self care where appropriate and rationalising the number of ocular lubricants each patient is prescribed) would produce savings in the order of £20.2million. This equates to £27,085 per 100,000 population.**
- **Simple eye ointment by 80% could save a further £531,857 annually. This equates to £714 per 100,000 population.**

A breakdown of the annual savings by country is available in table 2.

Table 2. 12 months cost avoidance by country (NHSBSA (Oct-Dec 2023) and Public Health Scotland (Aug-Oct 2023)

Country	12 months cost avoidance (£)		
	Branded glaucoma preparations - 20% prescribing reduction	Ocular lubricants - 20% prescribing reduction	Simple eye ointment - 80% prescribing reduction
England	£5,811,579	£16,661,876	£490,678
Scotland	£804,233	£1,766,832	£19,619
Wales	£452,508	£1,205,461	£15,678
Northern Ireland	£150,188	£508,922	£5,258
Isle of Man	£18,680	£18,570	£624
Total	**£7,237,188**	**£20,161,661**	**£531,857**

Summary

Updated NICE guidance gives 360° SLT a more prominent role in the management of glaucoma, but topical eye preparations remain a significant part of the treatment pathway for many people.[7] Generic eye preparations should be recommended where appropriate, given the potential cost savings.[7,15] Primary care health professionals can support correct instillation technique and treatment adherence, which are key issues in glaucoma treatment.[15]

A wide choice of ocular lubricants is available for managing dry eye disease.[26] Mild to moderate cases of dry eye disease or sore tired eyes are usually suitable for self care with lifestyle modifications and purchased OTC ocular lubricants (if needed).[33] Where prescribing is appropriate, formularies should support prescribers to select suitable, cost-effective dry eye disease treatments.

For both conditions, preservative-free options should be available.[7,26] Given their greater cost, local guidance should be agreed to target their use to those groups of patients most likely to benefit.

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Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-344-eye-preparations/
Implementation tools	
Data pack	https://data.prescqipp.info/views/B344_Managementofdryeyesinprimarycareeyepreparations/FrontPage?%3Aembed=y&%3Aiid=1&%3AisGuestRedirectFromVizportal=y

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