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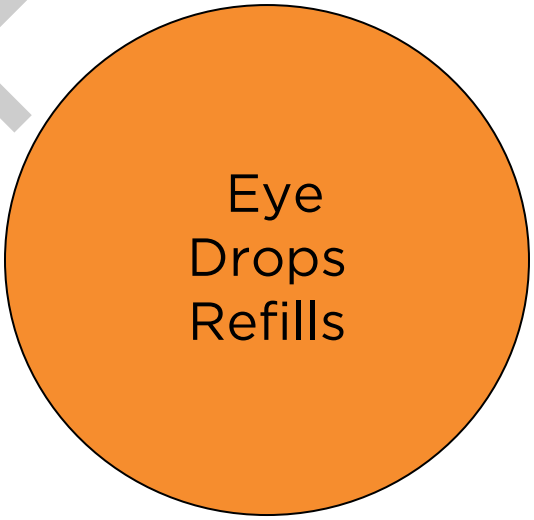
Secretariat for State Affairs

Early Eye Drop Prescription Refill Legislation

Resource materials to support state legislative campaigns



John Peters, MD, Secretary for State Affairs
Laura Green, MD, Associate Secretary for State Affairs
Rachel Reinhardt, MD, Associate Secretary for State Affairs

Model Legislation

AN ACT relating to prescription eye drops.

SECTION 1:
BE IT ENACTED BY THE STATE LEGISLATURE:

(1.) Any health benefit plan issued or renewed on or after the effective date of this Act that provides coverage for prescription eye drops shall not deny coverage for a refill of a prescription if:
a. The refill is requested by the insured:
1. For a thirty (30) day supply, between twenty-one (21) and thirty (30) days from the later of:
(i). The original date the prescription was distributed to the insured; or
(ii.) The date the most recent refill was distributed to the insured; and
2. For a sixty (60) day supply, between forty-two (42) and sixty (60) days from the later of:
(i). The original date the prescription was distributed to the insured; or
(ii.) The date the most recent refill was distributed to the insured; and
3. For a ninety (90) day supply, between sixty-three (63) and ninety (90) days from the later of:
(i). The original date the prescription was distributed to the insured; or
(ii.) The date the most recent refill was distributed to the insured; and
b.) The prescription eye drops prescribed by the practitioner are a covered benefit under the policy or contract of the insured, and;
c.) The prescribing practitioner indicates on the original prescription that additional quantities of the prescription eye drops are needed, and:
d.) The refill requested by the insured does not exceed the number of additional quantities needed.

(2.) This Section shall, to the extent practicable, be limited in quantity so as not to exceed the remaining dosage initially approved for coverage, provided further that such limited refilling shall not limit or restrict coverage with regard to any previously or subsequently approved prescription for eye drop medication and shall be subject to the terms and conditions of the policy otherwise applicable to this coverage.

SECTION 2:
BE IT FURTHER ENACTED, that this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after (XXXX Date)

SECTION 3:
AND BE IT FURTHER ENACTED, that this Act shall take effect (XXXX Date)

Early Eye Drop Refill Legislation Statement

Many patients rely on a variety of prescription eye medications for the preservation of sight. particularly, those suffering from glaucoma and other degenerative eye diseases require prescription eye drops on a daily basis. The effectiveness of prescription eye drops relies heavily upon continuity of treatment, specifically consistent daily usage by the patient.

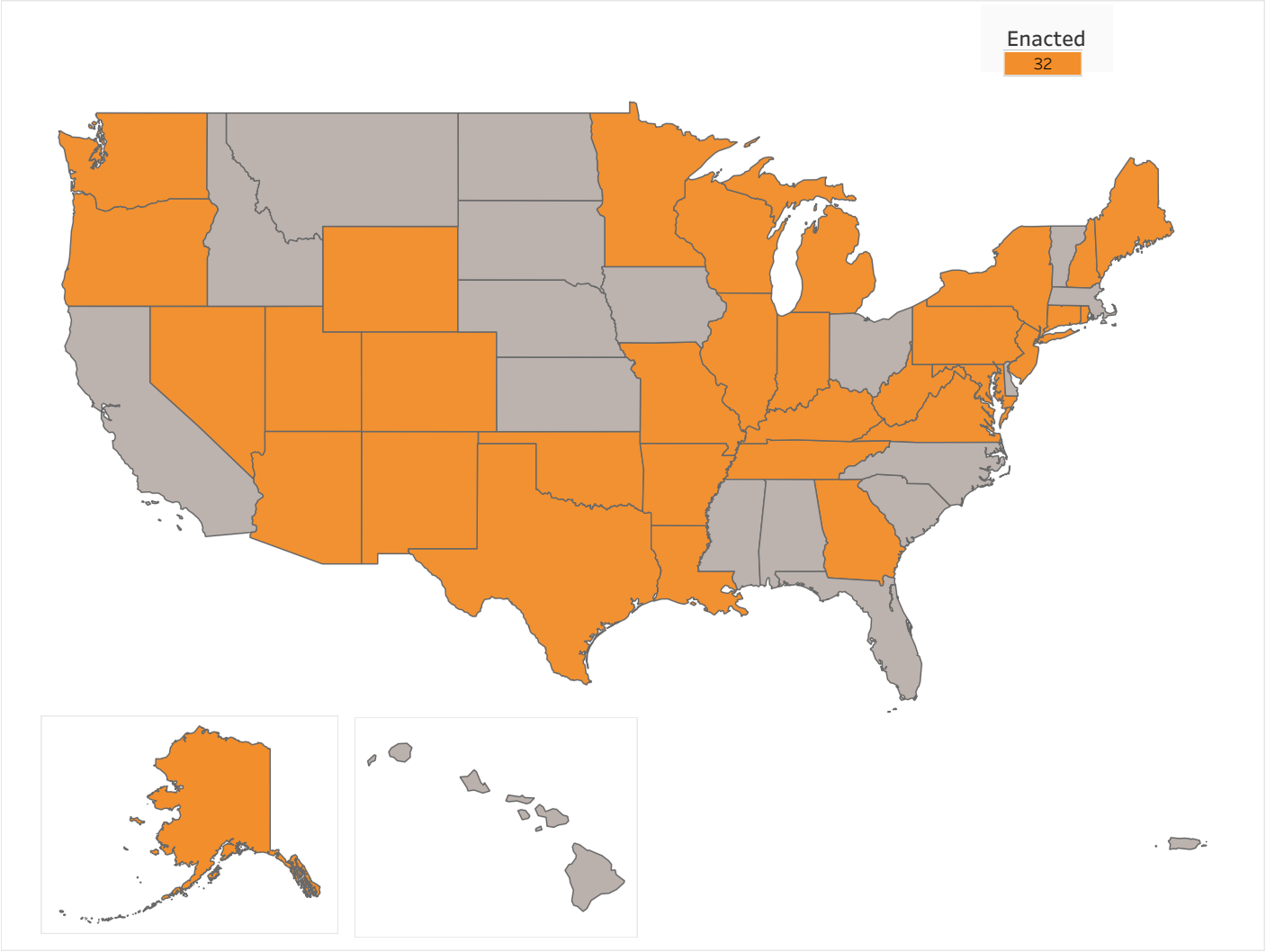
Presently, many patients run out of their prescription eye drops well before the expiration of the intended period of use denoted on the prescription label. This is particularly problematic for elderly patients with unsteady hands. However, even those using the utmost care in storing and using the eye drops find it nearly impossible to ration the medication to last the period of intended use. When a patient runs out of their prescription prior to the expiration of the intended period of use and returns to their pharmacist seeking a refill of the prescription, coverage is denied by the insurance company and the patient is turned away empty handed.

Furthermore, many of these medications are not yet available in generic form and are very costly, thereby prohibiting patients from paying for the necessary prescription out of pocket which disproportionately burdens our elderly and infirm. Unfortunately, many patients are unable to utilize the entirety of the medication because of shaky hands or a defect in the products' dispensing mechanism. This bill would correct the problem by allowing for authorized refills of the product.

Failing to provide sensible refill and insurance coverage policies, prohibits continuity of care and puts patients at risk. Therefore, to ensure that patients who have prescription drug coverage continue to receive this important treatment it is necessary to require coverage for the limited refilling of prescription eye drops without regard to coverage restrictions for early refill of renewals. This legislation will provide much needed protections for those who rely on prescription eye drops for preservation of sight.

29 states have already passed Early Eye Drop Refill Laws. In addition, the Centers for Medicare and Medicaid Services (CMS) has issued guidance to Medicare Part D sponsors on the application of early eye drop refills for Medicare beneficiaries.

Early Eye Drop Refill Laws



SAMPLE Press Release – Early Eye Drop Refill

Date
FOR IMMEDIATE RELEASE CONTACT: (*Name, Contact info)*

(State) Ophthalmologists Push for Legislation Ensuring Continued Access to Sight-Saving Medications

(State) ophthalmologists are supporting legislation recently introduced in the (STATE LEGISLATURE, ADD BILL #), which would ensure patient insurance coverage for early refills of prescription eye drops by prior to the expiration of the intended period of use.

Just as insurance companies require pharmacies to dispense the specific number of pills as prescribed by a physician for a certain time period, they must also dispense the exact volume of eye drops as prescribed. But unlike pills, eye drops are a less reliable drug delivery system. Many adults suffering from glaucoma and other degenerative eye diseases are required to use daily prescription eye drops which are essential for the preservation of their eyesight. It is not uncommon for older patients or patients with physical disabilities to run out of their prescription well before the renewal period. This is primarily due to visual impairments and other difficulties in effectively administering the drops.

It often may take patients several tries before one drop is placed correctly into the eye, which leads to an empty bottle before they can renew the prescription. When patients run out of their prescription prior to the renewal date and try to get it refilled, coverage is denied by the insurance company. In these instances, patients are turned away empty handed even though an interruption in treatment could cause their eyesight to deteriorate. (State) ophthalmologists are encouraging state lawmakers to pattern with the enactment of (BILL #).

"Failing to provide sensible refill and insurance coverage policies continue to prohibit continuity of care and puts patients at risk," said (NAME, MD), president of the (STATE SOCIETY). "Therefore, to ensure that patients who have prescription drug coverage can continue to receive this important treatment, it is necessary to require coverage for the limited refilling of prescription eye drops without regard to coverage restrictions for early refill of renewals," added (NAME).

Twenty-nine other states have worked with the medical community to preserve patient access to sight-saving medication by enacting legislation similar to (Bill #). In those states, patients with commercial drug plans are now allowed to refill their eye drop medications prior to the refill date on the prescription label. On the federal level, Medicare Part D drug plans now allow an override of the refill limits when patients seek to refill their eye drop prescription at 70% of the predicted days of use, which would be day 21 for a 30-day supply. In addition, physicians can now request authorization for even earlier refills for patients in need.

"Enactment of similar policies in (STATE) will provide much needed protections for those who rely on prescription eye drops for preservation of sight, and I urge our legislators across (STATE) to get behind this bill and pass it into law," said (SOCIETY PRESIDENT).

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AMERICAN ACADEMY™
OF OPHTHALMOLOGY

AMERICAN GLAUCOMA SOCIETY

AAO and AGS Joint Statement on Glaucoma Eye Drop Availability

Changes in our health care system continue to create unintended consequences for glaucoma patients who rely upon pharmaceutical benefit plans to provide their glaucoma medications. Eye drops are different than pills. Eye drops are difficult to administer by over 2/3 of patients with many having trouble accurately administering a single drop onto their eyes. Many of these patients are faced with the additional difficulties of early refill denials due to quantity restrictions, lack of access to certain medications due to limited formularies, and high out-of-pocket copays.

Chronic medical therapy of glaucoma is a critical and cost-effective first line of treatment. Gaps in the treatment of glaucoma can lead to vision loss and blindness. This statement is submitted on behalf of members of the American Glaucoma Society (AGS), an organization of over 700 ophthalmologists who specialize in glaucoma care and surgery, and the American Academy of Ophthalmology (Academy), the world's largest association of over 29,000 eye physicians and surgeons. We are committed to providing optimum care for the glaucoma patient.

Background

Pharmacy benefit programs with Medicare Part D, and non-Medicare commercial health insurance plans, typically have strict limitations on the frequency of medication refills prescribed for chronic conditions. Plans restrict patients from refilling medications earlier than the single month or 90-day refill date. The number of drops in various bottles of glaucoma medications is known, assuming a constant bottle angle and pressure on the bottle. Despite the fact that bottles may contain more drops than the labeled quantity, there are numerous reports of patients running out of drops prematurely and patients unable to obtain refills under their plans prior to the allowed refill date. The current monthly volumes of eye drops allowed by health plans are often inadequate due to common and inadvertent wastage of drops when eye drops are applied. Often this leads to patients either stretching out their eye drop prescription (e.g., taking a twice daily medication once a day) or discontinuing their use of eye drops until the next allowable refill under their drug plan; creating a gap in care where the patient's disease may worsen.

The AGS and Academy are very concerned about inadequate access to necessary medication for chronic glaucoma treatment. In 2009, and again in 2010, our organizations approached the oversight committee for the Medicare Part D drug plans and were able to effect changes that resulted in an easing of the refill restrictions. Medicare Part D drug plans now allow an override of the refill limits when patients seek to refill their eye drop prescription at 70% of the predicted days of use, e.g., at day 21 for a 30-day supply. In addition, physicians can now request authorization for even earlier refills for patients in need.

Eight state ophthalmology societies have been successful in working with their state legislators to enact laws, enabling patients to refill their eye drop medications on demand for commercial drug plans as of 2014. While these activities have helped alleviate some of the barriers to eye drop medication access in some populations, the AGS and Academy hope to eliminate refill access problems for all patients. The AGS and Academy entreat health insurers with pharmacy benefit plans, and their pharmacy benefit managers, to study this issue further and re-evaluate their refill policies for eye drop medications. The AGS and Academy would be delighted to assist with this process.

Formulary Management

Restricted and tiered formularies for glaucoma eye drop medications have become standard policy for all pharmaceutical benefit plans in Medicare Part D and commercial insurances. Various strategies are employed to incentivize patients and encourage providers to use the least expensive glaucoma medication. Some drugs are restricted by "quantity limits" and are subject to the concerns we described above. Other drugs are restricted by "step therapy" that requires physicians to prescribe and document the discontinuance of a lower-tier drug before allowing access to a higher-tier medication. Finally, some drugs are placed in a prohibitively high-cost tier. Because each drug plan formulary is different, this information is often lacking to both the physician and patients until the patient presents their prescription to their pharmacist, although some electronic prescribing systems now provide tier-level information for some plans. Pharmacists, however, have direct patient-specific access to tier-level copay amounts, deductibles, drug plan prior authorization fax numbers and addresses, while physicians do not. This limits our members' ability to counsel patients about drug costs and restrictions. Step-therapy often requires multiple interactions with the drug plan on the part of the physician to provide records, sometimes from many years prior, to prove to the plan that the patient has tried and failed a particular therapy. During this time-consuming process, the patient is denied access to needed medications.

A particularly troubling feature of formulary management is the ability for drug plans to switch tiers for their drugs on a yearly basis. The most common scenario is for brand name drugs within the same class to be moved back and forth from one tier to another, presumably due to the negotiated costs and rebates of the drug. The workflow cost to an insurer making a formulary tier change within class is negligible, while the cost to a physician's practice is high. Managing phone calls from patients and pharmacists who want to avoid the higher copay or are concerned about a change in medication, rewriting and authorizing prescriptions, and educating patients and fielding their questions about a medication change and potential side effects is time-consuming and costly to a practice, while achieving no real benefit for the patient. In addition, if a change in medication is made, patients must return to the office for an earlier re-evaluation, increasing health care spending (often more than the price differential to the pharmacy plan).

The AGS and Academy ask the pharmacy benefit managers to carefully evaluate their formulary changes with these issues in mind, ensuring that both physicians and patients have timely access and reasonable cost for their glaucoma medications. Plans should consider a system whereby a patient who has had documented success with a particular medication in a prior year is allowed to continue at the same or lower tier-level copay in subsequent years.

In addition, the Academy, along with other medical organizations, has suggested that the Center for Medicare and Medicaid Services (CMS) create a billing code that would reimburse a physician whenever the practice is managing a drug prescription issue that develops solely due to a formulary change from an insurer.

Summary

In the United States, there are millions of patients treated with topical eye medications each year. In the treatment of glaucoma, almost 75% are treated with more than one medication simultaneously for long periods of time, often years. It has long been recognized that non-adherence is a significant roadblock to successful treatment of patients even when appropriate medications are easily available. Inadequately treated glaucoma leads to irreversible vision impairment and blindness. Although there are patients who are vigilant in taking their eye drops regularly and on schedule, ophthalmology is relatively unique, however, as even compliant patients may not be able to administer eye drops correctly and may waste a significant volume every day. Unlike pills, eye drops are difficult to use and are a less reliable drug delivery system. We have found that, even in experienced glaucoma patients who self-administer their eye drops, between 53–61% regularly administer more than one drop at a time, many without even realizing it. These numbers are increased in those with poor vision from glaucoma, cataract, or retinal diseases. Eighty percent of these patients with visual comorbidities are unable to adequately instill a single eye drop at a time.

Physical disabilities can also interfere with the administration of eye drops. It is particularly difficult for older patients to master and perform this task proficiently. Eye drop administration requires both the technical ability to easily squeeze out a single drop and the hand-eye coordination to find the eye and squeeze the drop onto the eye. Regrettably, especially in older individuals where glaucoma is more common, diseases such as arthritis, tremor, Parkinson disease, and other neurological and musculoskeletal problems make it difficult to accurately squeeze the bottle to administer just a single drop. It is not uncommon for some patients to require double the allowed volume.

Ophthalmologists are increasingly aware that restrictions on medication availability are a component of poor outcomes in glaucoma treatment. It is well recognized that increased cost is associated with lack of adherence. Expecting the patient to pay full retail prices out-of-pocket for additional medication to cover the refill gap or for non-formulary medications is unrealistic, even if the patient is made aware that such an option exists.

High copays for drugs and increasingly popular high-deductible insurance plans will likely exacerbate patient concerns about drug costs in the future. Physicians and patients should have direct, easy access to all the cost information available for all drug plans in real-time, including links to online authorization portals for all drug plans.

Glaucoma patients who go untreated, even for relatively short periods of time, run the risk of worsening vision loss and increased likelihood of requiring surgical intervention for their disease. Surgical intervention carries far greater risk than chronic medical therapy and increases health care costs. Vision loss from glaucoma has been associated with an increase in the rates of falls, depression, difficulty with facial recognition, inability to drive, reading difficulty, reduced physical activity, and nursing home admissions.

The AGS and Academy entreat health insurers with pharmacy benefit plans and their pharmacy benefit managers to study these issues further and re-evaluate their refill and formulary tiering policies for eye drop medications. Strategies to increase eye drop availability should be immediately instituted to prevent interruption and gaps in treatment for our patients.

Approved by: American Glaucoma Society, June 2009; revised and approved January 2014

American Academy of Ophthalmology, Quality of Care Secretariat, June 2009; revised and approved January 2014

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group

Jeffrey Kelman, M.D., Chief Medical Officer

DATE: June 2, 2010

SUBJECT: Early Refill Edits on Topical Ophthalmic Products

The Centers for Medicare & Medicaid Services (CMS) is re-issuing this guidance based on complaints we have received regarding the application of early refill edits (i.e. refill-too-soon edits) to topical ophthalmic products. CMS recognizes that early refill edits are an important utilization management tool used to promote compliance and prevent waste. However, it is equally important that Part D sponsors implement such edits in a manner that does not unreasonably put beneficiaries at risk of interruptions in drug therapy that potentially have serious consequences.

Part D sponsors need to take into consideration differences that some dosage forms, such as topical ophthalmics, present when establishing early refill edits. Edits based on an algorithm that is appropriate for tablets and capsules are not necessarily appropriate for other dosage forms for which administration is not as easily measured and controlled. This is not to say that Part D sponsors should not implement early refill edits for such medications, especially given that these edits can identify inappropriate use, but it does mean that such edits need to reasonably accommodate waste that can be anticipated given the nature of these products and their self-administration among the Medicare patient population. Part D sponsors also should be prepared to allow overrides of these edits on a case-by-case basis when appropriate and necessary to prevent unintended interruptions in drug therapy.

To assist Part D sponsors in determining proper edits to protect beneficiary access CMS recommends that sponsors allow the following for topical ophthalmic products:

- Permit refills at 70% of the predicted days of use. By way of an example, for a prescribed medication with an expected duration of 30 days of use, the refills would be permitted at day 21.
- Ensure that the refill allowances are the same regardless of purchase through retail or mail-order sources.

- Permit physicians to authorize earlier refills than 70% days of use for particular beneficiaries who continue to have difficulty with inadvertent wastage.

If you have any questions regarding this guidance, please contact Keely Ireland at 410-786-7160 or keely.ireland@cms.hhs.gov.