REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 4-A-16

Subject: Access to Self-Administered Medications

Presented by: Robert E. Hertzka, MD, Chair

Referred to: Reference Committee A
(A. Patrice Burgess, MD, Chair)

At the 2015 Annual Meeting, the House of Delegates adopted Policy D-120.942, directing the American Medical Association (AMA) to study the prevalence of medication dispensing and refill restrictions on ophthalmic and other "difficult to dose" medications and the effect they have on patient care when medically necessary refills are denied or delayed due to the arbitrary determination by non-physicians of what actually constitutes a one or three month supply of ophthalmic and other medications. The study directed in Policy D-120.942 was assigned to the Council on Medical Service for a report back at the House of Delegates 2016 Annual Meeting.

This report provides background on self-administered medications, reviews health insurance coverage of self-administered medications, summarizes AMA policy and advocacy efforts, discusses the appropriate avenues for addressing the denial of early refills for difficult to dose medications and presents policy recommendations.

SELF-ADMINISTERED MEDICATIONS

The majority of ophthalmic medications are delivered topically via eye drops, which can create difficulties when patients attempt to self-administer the correct dosage. Patients may lack the manual dexterity to administer their own eye drops, have medical conditions that make it hard to hold the bottle steady, have poor hand-eye coordination and/or suffer from poor eyesight.

An estimated 57 percent of patients regularly administer more than one drop at a time.[1] When waste occurs and prescriptions run out before the refill date, patients have experienced denials for early refills by health insurance companies. Patients who are concerned about running out of eye drops may take less than the prescribed daily dose to make the prescription last longer and/or experience a lapse in medication until their health insurance company allows the next refill. Without continuous access to prescription eye drops, patients with glaucoma and other degenerative or inflammatory eye diseases risk further degeneration or vision loss.

INSURANCE COVERAGE

Medicare Part D pharmacy benefit management (PBM) companies and commercial health insurance companies typically impose strict limits on the frequency of medication refills. The American Academy of Ophthalmology (AAO) has advocated for access to necessary medications for chronic glaucoma treatment. In 2009, working with other eye health organizations, the AAO began recommending that prescription eye drop refill policies should be more flexible. As a result, Medicare Part D drug plans now allow an override of the refill limits when patients request a refill

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of their eye drop prescription at 70 percent of the predicted days of use, e.g., at day 21 for a 30-day supply. In addition, physicians can request authorization for earlier refills.

Advocacy at the state level has also been effective. As of July 2015, 18 state ophthalmology societies, in partnership with the AAO, have been successful in working with their state legislators to pass legislation allowing patients with commercial drug plans to refill their eye drop medications prior to the prescription refill date.

RELEVANT AMA POLICY AND ADVOCACY

The AMA opposes PBM companies'interference in the provision of medical care by physicians (Policies D-125.997 and H-125.986[4]). As expressed in Policy H-120.943, health plans should define a one month's supply of medication as a minimum of 31 days and a three month's supply as a minimum of 93 days so that patients have an adequate supply of their prescription medication. Prescription refills should provide the appropriate number of doses for the time period specified by a patient's physician. Policy H-120.952 opposes limitations on the legitimate, clinically appropriate refill of patient prescriptions, such as restricting the refill date or imposing less than a 90-day supply of a prescription refill for chronic conditions.

The AMA is working with the National Association of Insurance Commissioners to revise its model bill on PBMs to encourage greater transparency of their activities and greater deference to physicians' clinical judgment in utilization management appeals and exceptions.

DISCUSSION

The request for the AMA to study the prevalence of medication dispensing and refill restrictions on ophthalmic medications does not appear necessary or within the AMA's purview. It is clear that advocacy efforts by the appropriate specialty societies have improved Medicare coverage policies and is improving state coverage policies in a manner supported by the intent of Resolution 504-A-15 (Policy D-120.942).

Another element of the requested study was to determine the effect on patient care when medically necessary refills are denied or delayed. The impact on patient care, such as risking further degeneration of a patient's illness and interfering in the patient-physician relationship, has been clearly enumerated and detailed by the AAO.

In response to the request to also study other "difficult to dose" medications, the Council recommends that the AMA support legislation that prohibits health insurance and PBM companies from denying early prescription refills for solutions, ointments, gels, creams, nasal sprays and other formulations that are difficult and/or imprecise to self-administer and therefore may be completely used prior to their refill date. One exception should be for controlled substances as there could be valid reasons to deny an early refill.

The Council believes that organizations with clinical expertise on the medical conditions that necessitate prescriptions for solutions, ointments, gels, creams, nasal sprays, and other formulations that are difficult and/or imprecise to self-administer should lead advocacy efforts to increase access to these medications. As the AAO is already addressing the concerns raised in Policy D-120.942, the Council recommends that the AMA support and encourage interested national medical specialty societies and other stakeholders to continue to advocate on the state level and work with health insurance and PBM companies to re-evaluate their refill policies on medications that are difficult and/or imprecise to self-administer to allow for early refills as needed.

The Council recommends reaffirming Policies D-125.997, H-120.952 and H-120.943, which oppose both the interference by PBM companies into the practice of medicine and restrictions on prescription refills, and support an adequate supply of prescription medications.

Finally, the Council recommends rescinding Policy D-120.942, which calls for the study that has been accomplished by the development of this report.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed:

1. That our American Medical Association (AMA) support legislation that prohibits health insurance and pharmacy benefit management (PBM) companies from denying early prescription refills for solutions, ointments, gels, creams, nasal sprays, and other formulations that are difficult and/or imprecise to self-administer. (New HOD Policy)

2. That our AMA support and encourage interested national medical specialty societies and other stakeholders to continue to advocate on the state level and work with health insurance and PBM companies to re-evaluate their refill policies on medications that are difficult and/or imprecise to self-administer to allow for early refills as needed. (New HOD Policy)

3. That our AMA reaffirm Policies D-125.997, H-120.952 and H-120.943, which oppose both the interference by PBM companies into the practice of medicine and restrictions on prescription refills, and support an adequate supply of prescription medications. (Reaffirm HOD Policy)

4. That our AMA rescind D-120.942, which requested this report. (Rescind HOD Policy)

Fiscal Note: Less than $500.

REFERENCE

[1] American Academy of Ophthalmology and American Glaucoma Society Joint Statement on Glaucoma Eye Drop Availability. 2014. Available at: http://www.aao.org/clinical-statement/aao-ags-statement-on-glaucoma-eye-drop-availability