REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 3-I-26

Subject: Non-Medical Switching of Prescription Drugs

Presented by: A. Patrice Burgess, MD, Chair

Referred to: Reference Committee J

At the 2025 Interim Meeting, the House of Delegates adopted Policy H-125.971, "Non-Medical Switching," which states:

1. Our American Medical Association (AMA) opposes the practice of non-medical switching by pharmacy benefit managers (PBMs) and health insurers, except when clinically justified and approved by the prescribing physician.

2. Our AMA study and report back at I-26 on the clinical and economic impact of non-medical switching on patient outcomes, medication adherence, and overall healthcare utilization, and disseminate these findings to policymakers and the public.

This report provides an overview of non-medical switching of prescription drugs and its impact on patients, physicians, and the healthcare system overall; related AMA policies; and offers recommendations to amend and reaffirm AMA policy.

BACKGROUND

While there are valid medical reasons for a medication to be changed, such as treatment efficacy and adherence or if a patient is experiencing concerning side effects, these choices should be made collaboratively between the patient and physician, not by insurance companies or PBMs. When a drug is switched for reasons outside of medical necessity, often driven by payment or coverage changes, it is referred to as non-medical switching.[1] Typically, payers and PBMs force these switches in order to reduce their own costs.[1] Non-medical switches are generally done through direct changes in drug formularies, the negotiated list of covered drugs, or coverage structures and driven either by the PBM, payer, or a combination of each entity. However, on occasion, switches can be strongly encouraged or forced on patients through pharmacy changes or limitations imposed by patient assistance programs.[2,3] While similar, non-medical switching is distinct from a change from a brand name drug to its biosimilar/generic drug. Non-medical switching occurs when the payer or PBM requires that the patient switch to a different drug altogether instead of a generic, but identical, version.[1]

Estimates show that non-medical switching is a relatively frequent occurrence, with over 50 percent of physicians reporting their patients experienced it on a regular basis. Surveyed psychiatrists reported that over 60 percent of their patients prescribed psychoactive medications experienced non-medical switching "frequently or very frequently."[4] Further, physicians practicing in specialties that utilize higher cost drugs, such as dermatology, oncology, rheumatology, and cardiology, reported as many as 80 percent of patients prescribed certain classes of drugs experienced frequent non-medical switching.[4] As an example, in 2025 anti-obesity medication

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(AOM) tirzepatide Zepbound was replaced on CVS Caremark's formulary with AOM semaglutide Wegovy, resulting in approximately nine percent of all patients prescribed Zepbound switched from that medication.[5] This illustrates the impact that these switches can have not only on individual patients, but also on the overall prescription drug landscape.

IMPACTS OF NON-MEDICAL SWITCHING

While the most frequent justification for non-medical switching is cost reduction, research suggests that in the majority of cases, the switch ends up costing more. As biologics and other expensive specialty drugs are a frequent target for non-medical switching, payers and PBMs force patients to switch from the more expensive drug to a less expensive alternative, potentially saving the payer up to 90 percent.[6] Yet these savings are often not seen by the patient and if savings are passed on to the patient, savings are much less than the amount seen by payers or PBMs.[6] Research also shows that in the long-term these savings are not maintained,[6] with over 86 percent of patients reporting higher out-of-pocket spending for the medication they were switched to compared to the original medication.[7] Compared to patients whose medication was not non-medically switched, patients who experienced non-medical switching had significantly higher total costs, resulting in an average increase in spending of about $4,500 per person.[6,8] These costs largely stem from greater utilization of the healthcare system after the switch.[9] Research has shown that non-medically switched patients have higher rates of surgery, hospitalization, emergency department visits, and medication intake either through dose escalation or the addition of other medications after a non-medical switch occurs.[9,10] Further, these negative impacts can have disproportionate consequences for those in minority communities as barriers to care, such as economic inequalities and systemic biases, compound the issues related directly to non-medical switching.[11]

Beyond the potential for increased costs and health system utilization, patients often face significant negative consequences to their health and well-being from non-medical switching. Nearly 40 percent of patients report that the medication they were switched to was less effective and with more disruptive side effects than the medication they were previously taking.[12] Further, over half of patients reported medical complications as a result of the new medication.[12,13] Of those patients reporting adverse impacts of the new medication, over half reported impacts on work and regular hobbies/activities, with about 40 percent also reporting impacts on their ability to provide care for children or other family members.[12] As a result of higher cost and poorer outcomes, patients often abandon treatment plans, which regularly leads to detrimental impacts on the patient's health.[12,14] Beyond physical health, patients report significant decreases in their overall mental health and well-being. After experiencing a non-medical switch, a majority of patients reported experiencing significantly higher levels of frustration, confusion, anxiety, and depression as well as a lower quality of life.[10,12,14]

Not only does non-medical switching cost more and harm patients, but research suggests that non-medical switching may adversely impact the patient-physician relationship. While patients reported that they eventually felt aligned with their physician in fighting the switch, a majority reported initial negative feelings that had an undermining effect on the patient-physician relationship.[12] Further, physicians consistently report that non-medical switching is a significant administrative burden to their practice, as it requires additional time and effort to find new, effective medication for the patient. Physicians reported significant increases in non-visit patient interactions, staffing needs, and contact with payers/PBMs and pharmacies after a non-medical switch.[12,15] Many physicians report increases in job stress related to non-medical switching as a result of ethical concerns and being forced to take responsibility for the decision of the payer/PBM. Physicians also report significant increases in stress and frustration, especially related to a lack of practice autonomy and poorer patient health outcomes.[12,15]

LEGISLATIVE ACTIVITY

Advocates suggest that a federal non-medical switching law could be a factor in ensuring long-term prescription drug affordability for patients.[16] At a basic level, advocates suggest that legislation preventing non-medical switching should include assurances that patients will continue to be able to access a medication that is prescribed by their physician/non-physician provider for at least the duration of the plan's coverage as plans are typically reevaluated at renewal.[16] Further, it is argued that such legislation should be distinct from anti-step therapy legislation as the two issues are distinct. Non-medical switching occurs *after* a patient has a stable medication routine, whereas step therapy typically occurs *while* a patient is attempting to establish a medication routine.[16]

While there has been no federal legislation successfully passed to prevent non-medical switching, 18 states have enacted some type of legislative protection against non-medical switching. Of these states, 12 have laws that prohibit all non-medical switching and six have laws that prohibit non-medical switching provided the prescriber can demonstrate the switch is likely to be harmful or an ineffective treatment.[17,18] Illinois law requires that payers provide 60-day notice of any formulary change to patients and provide a clear exception process. Further, if the prescribing physicians or non-physician providers provide a certification that the prescribed medication is medically necessary, the payer must cover it without any cost change to the patient through the remainder of the plan year.[19] Similarly, Texas law has established specific guidelines that require formulary changes to occur only at plan renewal and ensures that if a drug was covered, the patient will continue to be able to access coverage through the term of their plan year and requires allowance for physician appeal of any change in coverage if medically necessary.[20] It is important to note that application of such state laws to self-funded/employer-sponsored health plans varies, meaning that in some cases legal protections may not extend to beneficiaries of these plans.

AMA POLICY AND ADVOCACY

The AMA has a robust body of policy designed to ensure that patients are able to receive the medication prescribed by their physician without interference from payers, pharmacies, or PBMs. Policy H-125.971 details AMA opposition to non-medical switching, unless the switch is approved by the prescribing physician and clinically justified. Policy H-125.995, states AMA opposition to any changes by pharmacies/pharmacists to medications and outlines advocacy efforts to ensure that physician prescriptions cannot be substituted without physician approval. Policies H-115.974 and H-120.918 outline AMA support for the development and implementation of guidelines that detail the physician's ability to ensure that a prescription be dispensed exactly as written. Similarly, Policy D-120.923 outlines AMA advocacy to ensure that physicians are notified of any changes to a prescription and the origin of the change. To address biosimilar substitution, Policy D-125.989 outlines advocacy to ensure that any switches from biologic to biosimilar drugs will be done with express authorization of the physician and agreement of the patient. Further, Policy H-125.991 works to ensure that formularies meet a basic standard and that substitutions are not made without physician and patient approval. Finally, Policy D-125.992 outlines AMA opposition to administrative burden in prescription medication prior authorization and urges payers to minimize its usage.

The AMA Advocacy Resource Center (ARC) has worked extensively to prevent pharmacy interference in prescribing and altering drugs when dispensing. Additionally, to fight opaque practices in drug pricing, the AMA has developed a grassroots campaign, Truth in Rx. This campaign advocates for drug pricing transparency through public education and grassroots advocacy to legislators and regulators. Additionally, the AMA has submitted several comment letters and provided testimony on the importance of maintaining physician autonomy in prescribing

and increased transparency in drug pricing and formulary creation. Finally, the AMA has advocated to regulators, legislators, and payers, to urge patient access to the prescribed medication and support increased transparency in drug pricing and PBM practices.

DISCUSSION

Non-medical switching occurs when a medication is switched, often by a payer or PBM decision, without medical justification. Although these changes are common and typically done to save money, the savings generally begin and end with the payer and/or PBM. Not only do patients not share in the savings, but research also suggests they may actually end up paying more in out-of-pocket expenses for the new drug. Patients are more likely to experience adverse health events, such as side effects, hospitalization, or surgery, and report poorer mental health and quality of life after a non-medical switch occurs. Further, patients report that the switch may harm their relationship with their physician as patients are commonly confused as to the source of the switch. Additionally, physicians report significant increases in administrative burden and increases in stress and frustration after a patient's non-medical switch.

Currently, legislation to limit non-medical switching has been enacted in a number of states, but there is no federal restriction on the practice. Since the AMA has strong policy opposing the practice of non-medical switching, the Council recommends three amendments to strengthen and update the policy. First, the Council recommends the removal of the second clause of Policy H-125.971 as it is completed by this report. Second, it is recommended that a new second clause be added that outlines AMA advocacy to ensure that payers and PBMs honor coverage and prior authorization determinations through the duration of the most recent prior authorization approval. This will work to ensure that payers and PBMs cannot force a switch through extra utilization management requirements in order to skirt non-medical switching prohibitions. Third, the Council recommends a new third clause to advocate for payers to continue coverage for a medication while internal and external appeals processes are being adjudicated, thus ensuring patients are not left without their medication due to insurance company procedures. Finally, to ensure that physicians are not met with undue administrative burdens around prescription drug prior authorization, the Council recommends the reaffirmation of Policy D-125.992 which opposes prescription drug prior authorization and advocates for reduced administrative burdens for physicians.

RECOMMENDATIONS

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

1. That our American Medical Association amend Policy H-125.971, "Non-Medical Switching," to read as follows:

    1. Our AMA opposes the practice of non-medical switching by pharmacy benefit managers and health insurers, except when clinically justified and approved by the prescribing physician.

    ~~2. Our AMA will study and report back at I-26 on the clinical and economic impact of non-medical switching on patient outcomes, medication adherence, and overall healthcare utilization, and disseminate these findings to policymakers and the public.~~

    2. Our AMA advocate that all payers and pharmacy benefit managers honor coverage and prior authorization determinations for a prescription drug through the term determined in the most recent prior authorization approval or the plan year, whichever is longer.

3. Our AMA advocate that coverage be continued for a medication that is to be switched until all appeals regarding the prescription are adjudicated. (Modify Current HOD Policy)

2. That our AMA reaffirm Policy D-125.992, which outlines opposition to administrative burden in prescription medication prior authorization. (Reaffirm HOD Policy)

Fiscal Note: Minimal

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Council on Medical Service Report 3-I-26
Non-Medical Switching of Prescription Drugs
Policy Appendix

Non-Medical Switching H-125.971

1. Our American Medical Association opposes the practice of non-medical switching by pharmacy benefit managers and health insurers, except when clinically justified and approved by the prescribing physician.
2. Our AMA will study and report back at I-26 on the clinical and economic impact of non-medical switching on patient outcomes, medication adherence, and overall healthcare utilization, and disseminate these findings to policymakers and the public. (Res. 811, I-25)

Opposition to Prescription Prior Approval D-125.992

Our American Medical Association will urge public and private payers who use prior authorization programs for prescription drugs to minimize administrative burdens on prescribing physicians. (Sub. Res. 529, A-05; Reaffirmation A-06; Reaffirmation A-08; Reaffirmed in lieu of Res. 822, I-11; Reaffirmed: CMS Rep. 1, A-21; Reaffirmation: A-22)

Therapeutic and Pharmaceutical Alternatives by Pharmacists H-125.995

The AMA opposes legislative attempts at any level of government that would permit pharmacists, when presented with a prescription for a drug product, to: (1) dispense instead a drug product that is administered by the same route and which contains the same pharmaceutical moiety and strength, but which differs in the salt or dosage form (pharmaceutical alternatives); and (2) dispense a drug product containing a different pharmaceutical moiety but which is of the same therapeutic and/or pharmacological class (therapeutic substitution). Our AMA will work with state medical associations to ensure that state pharmacy laws and medical practice acts are properly enforced so that treating physician's directions cannot be overruled or substituted without prior physician approval. (Res. 89, I-85; Reaffirmed by Sub. Res. 501, A-95; Reaffirmed by CLRPD Rep. 2, I-95; Appended by Res. 501, A-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 01, A-18)

Prescription Labeling H-115.974

1. Our American Medical Association recommends that when a physician desires to prescribe a brand name drug product, they do so by designating the brand name drug product and the phrase “Do Not Substitute” (or comparable phrase or designation, as required by state law or regulation) on the prescription; and when a physician desires to prescribe a generic drug product, they do so by designating the USAN-assigned generic name of the drug on the prescription.
2. Our AMA recommends that, except where the prescribing physician has indicated otherwise, the pharmacist should include the following information on the label affixed to the container in which a prescription drug is dispensed: in the absence of product substitution, (a) the brand and generic name of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; and (d) the name of the manufacturer or distributor.
3. Our AMA recommends that when generic substitution occurs: (a) the generic name (or, when applicable, the brand name of the generic substitute [“branded" generic name]) of the drug dispensed; (b) the strength, if more than one strength of drug is marketed; (c) the quantity dispensed; (d) the manufacturer or distributor; and (e) either the phrase "generic for [brand name prescribed]" or the phrase "substituted for [brand name prescribed]”.
4. Our AMA recommends that when a prescription for a generic drug product is refilled (e.g., for a patient with a chronic disease), changing the manufacturer or distributor should be discouraged to avoid confusion for the patient; when this is not possible, the dispensing pharmacist should satisfy the following conditions: (a) orally explain to the patient that the generic drug product being dispensed is from a different manufacturer or distributor and, if possible (e.g., for solid oral dosage forms), visually show the product being dispensed to the patient; (b) replace the name of the prior generic drug manufacturer or distributor on the label affixed to the prescription drug container with the name of the new generic drug

manufacturer or distributor and, show this to the patient; (c) affix to the primary label an auxiliary (sticker) label that states, "This is the same medication you have been getting. Color, size, or shape may appear different;" and (d) place a notation on the prescription record that contains the name of the new generic drug manufacturer or distributor and the date the product was dispensed. (BOT Rep. 1, A-95; Amended: CSA Rep. 2, I-99; Modified Res. 512, I-00; Reaffirmed: CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmed: Sub. Res. 509, A-07; Reaffirmed: CSAPH Rep. 01, A-17; Reaffirmation: A-19; Modified: Speakers Rep. 02, I-24)

Prescription Drug Dispensing Policies H-120.918

1. Our American Medical Association supports the development and implementation of clear guidelines and mechanisms to indicate that the quantity of a prescription should be dispensed only as written using such language as "dispense quantity as written" or "no change in quantity;".
2. Our AMA supports the development, implementation and/or use of electronic or other means of communication to provide cost and coverage information of various prescribing quantities at the point of care allowing physicians to make the best decisions with their patients regarding prescribed medication quantities. (CMS Rep. 05, A-23)

Automatic Pharmacy-Generated Prescription Requests D-120.923

Our American Medical Association advocates that pharmacy-generated requests for changes to a prescription (quantity dispensed, refills, or substitutions) clarify whether these requests are generated by the patient or patient's surrogates, or automatically by the pharmacy. (Res. 706, A-24)

Substitution of Biosimilar Medicines and Related Medical Products D-125.989

Our American Medical Association urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena:

1. Preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients;
2. Allow substitution when physicians expressly authorize substitution of a biologic or biosimilar product; and
3. In the absence of express physician authorization to the contrary, allow substitution of the biologic or biosimilar product when;

a. the biologic product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components; and
b. there are no data indicating clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product; and (c) the prescribing physician has been adequately notified by the pharmacist. (Res. 918, I-08; Modified: CSAPH Rep. 1, I-11; Modified: CSAPH Rep. 4, A-14; Modified: CSAPH Rep. 05, A-24; Reaffirmed: CMS Rep. 04, I-24)

Drug Formularies and Therapeutic Interchange H-125.991

It is the policy of the AMA:
(1) That the following terms be defined as indicated:
(a) Formulary: a compilation of drugs or drug products in a drug inventory list; open (unrestricted) formularies place no limits on which drugs are included whereas closed (restrictive) formularies allow only certain drugs on the list;
(b) Formulary system: a method whereby the medical staff of an institution, working through the pharmacy and therapeutics committee, evaluates, appraises, and selects from among the numerous available drug entities and drug products those that are considered most useful in patient care;
(c) Pharmacy & Therapeutics (P&T) Committee: an advisory committee of the medical staff that represents the official, organizational line of communication and liaison between the medical staff and the pharmacy department; its recommendations are subject to medical staff approval;
(d) Therapeutic alternates: drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class, and usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;
(e) Therapeutic interchange: authorized exchange of therapeutic alternates in accordance with previously

established and approved written guidelines or protocols within a formulary system; and
(f) Therapeutic substitution: the act of dispensing a therapeutic alternate for the drug product prescribed without prior authorization of the prescriber.
(2) That our AMA reaffirms its opposition to therapeutic substitution (dispensing a therapeutic alternate without prior authorization) in any patient care setting.
(3) That drug formulary systems, including the practice of therapeutic interchange, are acceptable in inpatient hospital and other institutional settings that have an organized medical staff and a functioning Pharmacy and Therapeutics (P&T) Committee, provided they satisfy the following standards:
(a) The formulary system must:
(i) have the concurrence of the organized medical staff;
(ii) openly provide detailed methods and criteria for the selection and objective evaluation of all available pharmaceuticals;
(iii) have policies for the development, maintenance, approval and dissemination of the drug formulary and for continuous and comprehensive review of formulary drugs;
(iv) provide protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products;
(v) provide active surveillance mechanisms to regularly monitor both compliance with these standards and clinical outcomes where substitution has occurred, and to intercede where indicated;
(vi) have enough qualified medical staff, pharmacists, and other professionals to carry out these activities;
(vii)provide a mechanism to inform the prescriber in a timely manner of any substitutions, and that allows the prescriber to override the system when necessary for an individual patient without inappropriate administrative burden;
(viii) provide a mechanism to assure that patients/guardians are informed of any change from an existing outpatient prescription to a formulary substitute while hospitalized, and whether the prior medication or the substitute should be continued upon discharge from the hospital;
(ix) include policies that state that practitioners will not be penalized for prescribing non-formulary drug products that are medically necessary; and
(x) be in compliance with applicable state and federal statutes and/or state medical board requirements.
(b) The P&T Committee must:
(i) objectively evaluate the medical usefulness and cost of all available pharmaceuticals (reliance on practice guidelines developed by physician organizations is encouraged);
(ii) recommend for the formulary those drug products which are the most useful and cost-effective in patient care;
(iii) conduct drug utilization review (DUR) activities;
(iv) provide pharmaceutical information and education to the organization's (e.g., hospital) staff;
(v) analyze adverse results of drug therapy;
(vi) make recommendations to ensure safe drug use and storage; and
(vii) provide protocols for the timely procurement of non-formulary drug products when prescribed by a physician for the individualized care of a specific patient, when that decision is based on sound scientific evidence or expert medical judgment.
(c) The P&T Committee's recommendations must be approved by the medical staff;
(d) Within the drug formulary system, the P & T Committee shall recommend, and the medical staff must approve, all drugs that are subject to therapeutic interchange, as well as all processes or protocols for informing individual prescribing physicians; and
(e) The act of providing a therapeutic alternate that has not been recommended by the P&T Committee and approved by the medical staff is considered unauthorized therapeutic substitution and requires immediate prior consent by the prescriber; i.e., authorization for a new prescription.
(4) That drug formulary systems in any outpatient setting shall operate under a P&T Committee whose recommendations must have the approval of the medical staff or equivalent body, and must meet standards comparable to those listed above. In addition
(a) That our AMA continues to insist that managed care and other health plans identify participating physicians as their “medical staff” and that they use such staff to oversee and approve plan formularies, as well as to oversee and participate on properly elected P&T Committees that develop and maintain plan formularies;

(b) That our AMA continues to insist that managed care and other health plans have well-defined processes for physicians to prescribe non-formulary drugs when medically indicated, that this process impose minimal administrative burdens, and that it include access to a formal appeals process for physicians and their patients; and
(c) That our AMA strongly recommends that the switching of therapeutic alternates in patients with chronic diseases who are stabilized on a drug therapy regimen be discouraged.
(5) That our AMA encourages mechanisms, such as incentive-based formularies with tiered co-pays, to allow greater choice and economic responsibility in drug selection, but urges managed care plans and other third party payers to not excessively shift costs to patients so they cannot afford necessary drug therapies. (BOT Rep. 45, I-93; Reaffirmed by Sub. Res. 501, A-95; Appended: BOT Rep. 7, I-99; Modified: Sub. Res. 524 and Reaffirmed: Res. 123, A-00; Reaffirmed: Res. 515, I-00; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: Res. 533, A-03; Modified: CMS Rep. 6, A-03; Modified: CSA Rep. 2, A-04; Reaffirmation I-04; Reaffirmed in lieu of Res. 535, A-05; Reaffirmed: BOT Action in response to referred for decision Res. 503, A-05; Reaffirmed: CMS Rep. 2, I-05; Reaffirmation A-06; Reaffirmation A-08; Reaffirmed: CMS Rep. 2, A-10; Reaffirmed: CMS Rep. 01, A-20)