OLR RESEARCH REPORT

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STEP THERAPY QUESTIONS

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You asked:

1. What is step therapy?
2. Are there federal requirements or prohibitions regarding the use of step therapy in Medicaid programs?
3. What would SB 857 (2013) have required for commercial insurers?
4. What do other states do in this area?

SUMMARY

Typically, step therapy requires that an insured try a first-line medication (often a generic) before receiving coverage for a second-line medication (usually a branded product), even if the insured's physician prefers the latter. Some insurance policies require a consumer to fail on one or more first-line medications before they are allowed access to the medication that his or her physician would have tried as an initial treatment.

It appears that there are no federal requirements or prohibitions regarding the use of step therapy under state Medicaid programs. However, federal law allows state Medicaid programs to subject any covered outpatient drug to prior authorization (step therapy often works in conjunction with prior authorization) (42 USCA § 1396r-8(d)(1)(a)).

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In contrast, there are restrictions on the use of step therapy for Medicare. A 2010 "call letter" (regulatory directive) from the federal Centers for Medicare and Medicaid Services:

1. generally limits step therapy to two trials and failures of formulary alternatives before providing access to the prescribed medicine and

2. prohibits plans from requiring an enrollee to try and fail on an off-label drug before providing access to a drug approved by the Food and Drug Administration for that condition.

In addition, Medicare Part D (prescription drug) plan formularies must include substantially all drugs used to treat a wide range of conditions and diseases, including depression, psychoses, convulsions, cancer, and AIDS. (See 42 C.F.R. §423.272(b)(2) and Medicare Prescription Drug Benefit Manual, Chapter 6, § 30.2.5.)

In its 2013 session, the Connecticut legislature considered SB 857, which was not adopted. The bill would have prohibited commercial health insurers from requiring insureds to use any alternative brand name prescription or over-the-counter drugs before using a brand name prescription drug prescribed by a licensed physician. It also would have prohibited policies requiring the use of step therapy from (1) requiring failure on the same prescription drug more than once or (2) imposing a copayment greater than the lowest cost copayment for preferred drugs in the same class. The legislature did adopt PA 13-234, which allows the Social Services (DSS) commissioner to establish a step therapy program for prescription drugs in the Medicaid program, subject to restrictions on how the program would operate.

Among the states that have adopted legislation on step therapy are Florida, Louisiana, New York, and Vermont; while Indiana and Michigan restrict the use of prior authorization for prescription drugs. Legislation limiting step therapy requirements was recently passed but vetoed in Maine. There is pending legislation in California that would authorize the use of step therapy, but restricts its use (a 2012 bill was passed but vetoed). The legislation in California, Louisiana, Maine, and Vermont apply to commercial insurers generally; that in Florida, Indiana, Michigan, and New York applies to Medicaid programs.

A 2011 literature review of studies of the impact of step therapy (seven commercial insurance programs and seven Medicaid programs) found that step therapy programs for drugs other than antipsychotics can provide significant savings through the greater use of lower-cost

alternatives and, to a lesser extent, reduced drug utilization. On the other hand, the review found that the savings and clinical impact of step therapy for antipsychotics are unclear given the research conducted to date.

A 2013 analysis of the pending California legislation by the California Health Benefits Review Program (a University of California office that conducts analyses for the legislature) found that while step therapy does not have the goal of preventing persons from receiving prescription medications, the preponderance of evidence suggests that this may occur for some persons. It also found that there is insufficient evidence to determine whether step therapy protocols directly affect health outcomes.

STEP THERAPY

Step therapy is widely used in commercial, Medicare, and Medicaid insurance plans as a cost-savings measure. For example, a step therapy approach may be used for non-steroidal anti-inflammatory drugs (NSAIDs), which are often used to treat conditions such as arthritis. Traditional NSAIDs are available in generic forms that can be effective in treating pain and inflammation but may cause stomach irritation and side effects. Newer, more expensive branded NSAIDs may be a better option for patients who have experienced side effects with a generic NSAID or who already have a gastrointestinal condition such as ulcers. An NSAID step therapy rule may require that a patient try a generic NSAID or provide documentation of a gastrointestinal condition before being allowed to fill a prescription for the newer, more expensive branded product.

A 2012 review by the Pharmacy Benefits Management Institute found that 56% of responding employers had commercial insurance plans with step therapy provisions for one or more types of drugs. Step therapy was most common for antidepressants (44%), followed closely by asthma drugs (41%), and drugs used to combat high cholesterol (40%). Other therapy classes that frequently use step therapy include the NSAIDs and proton pump inhibitors, which are used to reduce gastric acid production.

Step therapy may use an automated process that reviews a patient's prescription claims history to qualify him or her for coverage of the drug preferred by the prescriber without requiring the prescriber to undergo a prior authorization review process. If patients have the first-line drug in their claims history, they may automatically qualify for coverage of a second-line therapy without triggering a review for coverage. In addition,

this mechanism may use other available patient data (e.g., age, gender, other medications, or diagnosis) to qualify patients for coverage for a second-line drug without a prior authorization review.

MEDICAID

Medicaid is a federal-state program that pays for medical assistance for low-income individuals and families. Although pharmacy coverage is an optional benefit under federal Medicaid law, all states currently cover outpatient prescription drugs for all categorically eligible individuals and most other enrollees in their Medicaid programs.

Most state Medicaid programs have adopted preferred drug lists (PDL, also called formularies), making any medication not deemed "preferred" subject to prior authorization. States use prior authorization, in conjunction with a PDL, to encourage the prescribing of the most clinically appropriate and cost-effective drug within a specific therapeutic drug category. Under federal law, non-preferred products must be made available through a review process that must provide a response within 24 hours and allow for a 72-hour supply of the drug in emergency situations. The complexity of the prior authorization process determines the extent to which it encourages trials of preferred medications first (i.e., step therapy).

Step therapy requirements under Medicaid programs vary by state and by the prescribed drug or medical condition. Some states have broad step therapy requirements for program participants. For example, Pennsylvania has step therapy requirements for a wide variety of drugs, including NSAIDS, protein pump inhibitors, anticonvulsants, anti-depressants, and others. Other states have narrower requirements. Georgia requires insureds to fail on two older forms of antipsychotic medications before receiving newer antipsychotic agents such as clozapine, risperidone, or olanzapine. Indiana has a step therapy requirement for anti-hypertensives (i.e., drugs used to address high blood pressure).

CONNECTICUT SB 857 AND PA 13-234

SB 857 would have prohibited health insurers from requiring insureds to use any alternative brand name prescription or over-the-counter drugs before using a brand name prescription drug prescribed by a licensed physician. But, the policy could require the covered person to use a therapeutically equivalent generic drug before using a brand name drug prescribed by a licensed physician.

Under the bill, if a policy required the use of step therapy, it could not (1) require failure on the same prescription drug more than once or (2) impose a copayment greater than the lowest cost copayment for preferred drugs in the same class on any person covered under the policy who has satisfied, in the prescribing physician's judgment, the step therapy requirements of the policy. Under the bill, "step therapy" were protocols that establish specific sequences for prescribing drugs for a specified medical condition.

SB 857 was not adopted, but legislation with different provisions was. PA 13-234 allows the DSS commissioner to establish a step therapy program for prescription drugs in the Medicaid program. It allows him to condition payment for these drugs on a requirement that the drug prescribed be from the state's PDL before any other drug being prescribed. If implemented, any step therapy program must:

1. require that the patient try and fail on only one prescribed drug on the PDL before another drug can be prescribed and eligible for payment;

2. not apply to any mental health–related drugs; and

3. give the prescribing practitioner, when medications for the treatment of any medical condition are restricted due to the step therapy program, access to a clear and convenient process to expeditiously request an override by DSS of the restriction.

Under the act, DSS must expeditiously grant an override if the prescribing practitioner demonstrates that:

1. the preferred treatment required under step therapy has been ineffective in the treatment of the patient's medical condition in the past,

2. the drug required under the step therapy program is expected to be ineffective based on the patient's known relevant physical or mental characteristics and the known characteristics of the drug,

3. the preferred treatment required under the step therapy program will cause or will likely cause an adverse reaction or other physical harm to the patient, or

4. it is in the best interest of the patient to provide the recommended drug regimen based on medical necessity.

The step therapy program requirement may not run longer than 30 days, after which the prescribing practitioner may deem the treatment to be clinically ineffective for the patient. If he or she does this, the drug prescribed and recommended by the practitioner must be dispensed and covered under the Medicaid program.

According to DSS, the step therapy procedures are an extension of existing prior authorization protocols for requesting a drug not on the PDL. When a pharmacy submits a bill for a drug not on the PDL, the pharmacy benefit manager automatically looks back in the person's claims history to see if he or she has previously tried a preferred product. If he or she has, the system will automatically approve the drug that is not on the PDL without requiring the prescriber to obtain prior authorization. If the claims system does not show the use of the preferred product, the prescriber must obtain a prior authorization and justify why the non-preferred product is needed. But, if prior authorization is not obtained, the pharmacy can provide a one-time 14-day supply until the prescriber requests and obtains a prior authorization. Once this authorization is obtained or the prescriber decides the individual can use the preferred product, the individual will be able to obtain their next refill after using their 14-day prescription.

OTHER STATES

At least eight states have passed legislation on the use of step therapy in commercial or Medicaid insurance plans.

Medicaid Programs

Florida. The law requires the state Medicaid agency to implement a step therapy prior authorization approval process for medications excluded from its PDL. Medications listed on the PDL must be used within the previous 12 months before the alternative medications that are not listed (Fla. Rev. Stat. § 409.912).

The step therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling, with the trial period between the specified steps varying according to the medical indication.

A drug may be approved without meeting the step-therapy criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

1. there is not a drug on the PDL to treat the disease or medical condition that is an acceptable clinical alternative;

2. the alternatives have been ineffective in treating the beneficiary's disease; or

3. based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

The Medicaid agency has established step therapy requirements for certain drugs. For example, before an insured can be covered for Celebrex (used to treat rheumatoid arthritis) he or she must have first failed two preferred NSAIDs.

Indiana. With certain exceptions, Indiana law prohibits prior authorization requirements under the state's Medicaid program for mental health drugs, such as antianxiety, antidepressant, or antipsychotic drugs. On the other hand, prior authorization is required for a brand name drug that a prescriber determines to be "medically necessary" when there is a generic equivalent (Ind. Code § 12-15-35.5-3).

Michigan. Michigan law restricts the use of prior authorization under Medicaid. These restrictions do not apply to drugs being provided under a contract between the Department of Community Health and a health maintenance organization (Mich. Comp. Laws § 400.109h).

Under the law, prior authorization is a departmental process that conditions, delays, or denies the delivery of pharmaceutical services, using predetermined criteria, to Medicaid beneficiaries it covers on a fee-for-service basis or under a contract. The process may require a prescriber to (1) verify with the department that the proposed use of a prescription drug meets the criteria for a prescription drug that is otherwise covered or (2) obtain its authorization before prescribing or dispensing a prescription drug that is not included on a PDL or that is subject to special access or reimbursement restrictions.

The law prohibits a prior authorization requirement for the following types of prescription drugs:

1. anticonvulsants, antidepressants, antipsychotics, or an antianxiety drug in a generally accepted standard medical reference that is not a controlled substance;

2. a prescription drug that is cross-indicated for any of these drugs in a generally accepted standard medical reference;

3. under most circumstances, a prescription drug that is recognized in a generally accepted standard medical reference as effective in the treatment of conditions specified in the most recent diagnostic and statistical manual of mental disorders; and

4. a prescription drug that is recognized in a generally accepted standard medical reference for the treatment of and is being prescribed to a patient to treat HIV, AIDS, cancer, epilepsy or seizure disorder or as part of organ replacement therapy.

New York. Historically, New York's Medicaid program generally did not cover brand name drugs that have a federal Food and Drug Administration approved A-rated generic equivalent, unless a prior authorization was obtained. This provision did not apply to drugs covered by the Preferred Drug, Clinical Drug Review Program, and the Brand Less Than Generic programs.

However, legislation passed as part of the FY 14 budget establishes a "prescriber prevails" provision in the state's Medicaid Managed Care program. The provision applies to medically necessary prescription drugs in the anti-depressant, antiretroviral, anti-rejection, seizure, epilepsy, endocrine, hematologic, and immunologic therapeutic classes, including non-formulary drugs. It requires insurers to cover those drugs that are medically necessary and warranted in the prescriber's reasonable professional judgment. The prescriber must consult with the managed care provider in making this decision.

Medicaid plans will continue to develop formularies and may also administer prior authorization programs for these drug classes. Prescribers will still be required to supply plans with requested information and clinical documentation or both. As they do currently, plans will be able to provide a three-day supply of medication when necessary.

Pursuant to federal and contractual provisions, the plans will continue to be required to meet specified turnaround times (e.g., a 24-hour review of urgent requests under Medicaid). Additionally, notices will be sent to insureds and prescribers for prior authorization requests

where the plan cannot make a determination (1) due to missing information or (2) if the prescriber's reasonable professional judgment has not been adequately demonstrated. In these cases, members' rights regarding appeals and fair hearings will continue to apply. This is consistent with plans' current processes for member and provider notification.

Further information about these provisions is available at http://www.newyorkhealthworks.com/wp-content/uploads/2013/06/Expand-Prescriber-Prevails-6-4-13.pdf.

Commercial Insurers

California. Legislation adopted in 2003 authorizes the Department of Health Services to establish step therapies for drugs and other items. In 2012, the legislature passed, but the governor vetoed, AB 369 which would have limited step therapy for pain medication to failures of two preferred drugs before allowing patients to receive other pain medications recommended by their physicians. The bill would also have allowed doctors to determine the duration of each step in the required treatments.

A related bill (AB 889) is currently pending. It would authorize health care service plans and health insurers to require step therapy when more than one drug is appropriate for the treatment of a medical condition, subject to specified requirements. The bill would require a plan or insurer that requires step therapy to have an expeditious process in place to authorize exceptions to step therapy when medically necessary and to conform effectively and efficiently with continuity of care requirements. The bill would require the duration of any step therapy or "fail first" protocol to be consistent with up-to-date peer-reviewed, scientific, medical and pharmaceutical evidence, and would, except under certain conditions, prohibit a health care service plan or health insurer from requiring that a patient try and fail on more than two medications before allowing the patient access to other medication prescribed by the prescribing provider, as specified.

The bill, with regard to an enrollee or insured changing plans or policies, would prohibit a new plan or insurer from requiring the enrollee or insured to repeat step therapy when that person is already being treated for a medical condition by a prescription drug, as specified. The bill would specify that these provisions would not apply to accident-only, specified disease, hospital indemnity, Medicare supplement, dental-only, or vision-only contracts or policies.

Louisiana. The law subjects health insurance plans to certain conditions it they (1) include prescription benefits and (2) use step therapy or fail first protocols (La. Rev Stat § 22:1053).

Specifically, when an insurer restricts the use of medications to treat any medical condition as part of a step therapy or fail first protocol, the prescribing physician must be given access to a clear and convenient process to expeditiously request an override of the restriction from the insurer. The insurer must grant an override if the physician can demonstrate to the insurer, based on sound clinical evidence, that the preferred treatment required under step therapy or fail first protocol:

1. has been ineffective in treating the insured's disease or medical condition,

2. is reasonably expected to be ineffective based on the insured's known relevant physical or mental characteristics and medical history and known characteristics of the drug regimen, or

3. will cause or will likely cause an adverse reaction or other physical harm to the insured.

The step therapy or fail first protocol can run no longer than the customary period for the medication when the physician demonstrates it to be clinically ineffective. When the insurer can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than the customary period for it to provide any relief or an amelioration to the insured, the step therapy or fail first protocol may be extended for an additional period of time no longer than the original customary period for the medication.

Maine. In its 2013 session, the Maine legislature passed, but the governor vetoed, LD 984. This bill would have required the clinical review criteria an insurer uses in approving prescription drugs to adhere to Food and Drug Administration prescription drug labeling. It would have barred such criteria from requiring failure on the same medication more than once for patients continuously enrolled in a health plan offered by the insurer.

It would have prohibited an insurer that requires failure on one or more drugs as a condition of prior authorization for a non-preferred drug from collecting a copayment greater than the lowest cost preferred drug copayment in the same drug class from an enrollee having satisfied the prior authorization requirements, as judged by the prescribing health care practitioner.

The bill would not have prevented a health care practitioner from prescribing a medication for an off-label use or from prescribing a medication on more than one occasion when the health care practitioner determines it is medically appropriate. Nor would it have precluded an insurer from collecting tiered copayments from enrollees not subject to the prior authorization requirements.

The bill would also have reduced, from two days to 24 hours, the amount of time insurers have to respond to non-emergency prior authorization requests. If an insurer failed to respond within 24 hours after receiving a completed request from a health care practitioner, the request would have been deemed to have been granted.

Vermont. H. 107C, passed in 2013, prohibits a health benefit plan offered by a health insurer or by a pharmacy benefit manager on behalf of a health insurer that covers prescription drugs and uses step therapy protocols from requiring failure on the same medication on more than one occasion for continuously enrolled members or subscribers. Neither can the insurer require, as a condition of coverage, use of drugs not indicated by the federal Food and Drug Administration for the condition diagnosed and being treated under a health care professional's supervision.

The act does not prohibit the use of tiered co-payments for members or subscribers not subject to a step-therapy protocol. Nor does it preclude a health professional from prescribing a medication for off-label use.

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