Step Therapy Provisions in Regional States

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Issue


Summary

Step therapy is a health insurance protocol establishing the sequence for prescribing drugs for specific medical conditions that generally requires patients to try less expensive drugs before higher cost drugs.

Connecticut law prohibits health carriers (i.e., insurers and HMOs) from requiring an insured to use a step therapy protocol for (1) more than 60 days or (2) any prescribed drug to treat stage IV metastatic cancer. Several bills in the last few years have sought to expand these exemptions; for example, HB 5275 (2022) would have also prohibited step therapy for drugs prescribed to treat mental or behavioral health conditions (HB 5275 (2022) died in the Appropriations Committee).

According to a 2021 study published in *Health Economics, Policy and Law*, 29 states have passed laws regulating step therapy in the individual and fully insured health insurance market. In general, these laws include time limits on how long step therapy can be required and a list of exemptions a patient or doctor can claim to override its requirements. Of these 29 states, only seven (including Connecticut) also regulate the use of step therapy in the state Medicaid plan.

Other than Connecticut, among the New England states, New Jersey, and New York, only Maine and New York broadly regulate how health carriers should use step therapy. As is the case in Connecticut, both Maine and New York allow patients meeting certain criteria to claim exemptions.
from step therapy requirements, such as for drugs that are likely to cause adverse reactions. Both Maine and New York include at least one additional exemption, not included in Connecticut law, that exempts drugs on which patients were stable prior to transferring health insurance plans. Only Connecticut appears to have a maximum time limit for which a patient can be required to try a step therapy protocol before applying for an exemption (i.e., 60 days).

**Connecticut**

**Fully Insured Commercial Health Insurance**

State law establishes the process for health care providers to request an exemption from the step therapy protocol described above. At the end of the 60-day period, or earlier for any drug prescribed to treat stage IV metastatic cancer, an insured’s health care provider can deem the drug clinically ineffective. In such a case, the law requires the health carrier to authorize the dispensation and coverage of the drug the health care provider prescribes, if it is covered under the policy. However, if the health care provider does not deem a drug clinically ineffective or request an override, the health carrier may continue the step therapy regimen.

*State law requires health carriers that use step therapy to (1) disclose the process by which a treating health care provider may request an override and (2) make it convenient to do so. Additionally, a request must be granted expeditiously if an insured’s health care provider demonstrates that the step therapy regimen:

1. has been previously ineffective in treating the insured;
2. is expected to be ineffective based on known relevant medical criteria and the insured’s individual medical characteristics;
3. will or is likely to cause an adverse reaction or physically harm the insured; or
4. is not in the insured’s best interest, based on medical necessity.

Although there is no timeframe specified in law, carriers must “expeditiously” grant a request based on one of the exemptions above. As with drugs that are exempt, once a health carrier grants an override request, it must authorize the dispensation of the drug and cover it, provided it is otherwise covered under the policy ([CGS §§ 38a-510 & 544](https://cga.ct.gov/Acts/1991/sca/21.htm)).

Additionally, the law requires health carriers to provide insureds a way to determine whether a prescription drug is covered by their specific health insurance plan, and if so, whether it requires step therapy regimen ([CGS § 38-477d](https://cga.ct.gov/Acts/1991/sca/21.htm)).
Medicaid

Connecticut law allows the Department of Social Services (DSS) commissioner to establish a step therapy protocol for drugs provided through the state’s Medicaid program. Such a protocol requires individuals to try a drug on the preferred drug list before another drug can be prescribed. By law, the step therapy protocol can by required for up to 30 days but drugs prescribed to treat mental health are exempt.

By law, the step therapy protocol must require that the:

1. patients try and fail only one preferred drug before another can be prescribed and
2. prescribing practitioner has a clear and convenient access to an override request process.

By law, DSS must grant an override request when the prescribing practitioner demonstrates that:

1. the preferred drug required by the step therapy protocol has been ineffective in treating the patient’s condition in the past;
2. the drug regimen required by the step therapy protocol is expected to be (a) ineffective based on the patient’s medical characteristics or (b) harmful to, or likely to, cause an adverse reaction in the patient; or
3. it is in the patient’s best interest to provide the recommended drug, based on medical necessity (CGS § 17b-274f).

Maine and New York

Maine and New York laws include step therapy exemptions similar to those under Connecticut law, but also include several additional exemptions as shown in Table 1 below.

### Table 1: Step Therapy Exemptions in Maine and New York

<table>
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<tbody>
<tr>
<td>The prescription drug is contraindicated, likely to cause adverse reaction or mental or physical harm</td>
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<tr>
<td>The prescription drug is expected to be ineffective based on the patient’s known clinical characteristics and the characteristics of the prescription drug regimen</td>
<td>The prescription drug is expected to be ineffective based on the patient’s known clinical history, condition, and prescription drug regimen</td>
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Table 1 (continued)

<table>
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<tr>
<td>The patient has already tried the drug (or any drug in the same pharmacologic class or with same mechanism of action) in their current or a previous health plan and it was discontinued due to lack of efficacy or effectiveness, a diminished effect, or an adverse reaction</td>
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</tr>
<tr>
<td>The prescription drug is not in the patient’s best interest, based on medical necessity</td>
<td>The prescription drug is not in the patient’s best interest because it will likely cause a significant barrier to their compliance with their plan of care or will likely worsen a comorbidity or decrease their ability to achieve or maintain reasonable functional ability to perform daily activities</td>
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<tr>
<td>The patient is stable on a prescription drug that was selected by their health care provider while they were covered under a current or previous health insurance plan</td>
<td></td>
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<tr>
<td>The prescription drug selected by the patient’s health care provider is used to assess or treat a serious mental illness</td>
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In New York, health plans must generally grant an exemption request within 72 hours, or 24 hours for patients with medical conditions that jeopardize their health without the specific prescription drug. New York additionally appears to prohibit step therapy requirements on any 12-month or less supply of a prescription contraceptive (NY Circular Letter No. 2003-1 (Supplement 3)).

Maine explicitly allows a health carrier to require an insured to try a generic version of a brand name drug (Me. Rev. Sta. Ann. tit. 24-a § 4320-N), and imposes additional restrictions on step therapy use for prescription drugs used to treat HIV (Me. Rev. Sta. Ann. tit. 24-a § 4317-D). Similar to New York, Maine requires carriers to respond to a complete exemption request within 72 hours (or 24 for exigent circumstances) (Me. Rev. Stat. Ann. tit. 24-A § 4320-N).

Other New England States

The other New England states regulate step therapy more narrowly.

New Hampshire requires nonquantitative treatment limitations, including step therapy, to be applied no more stringently for mental health treatments than it is for medical and surgical benefits (N.H. Code Admin. R. Ann. Ins § 2702.07). It also prohibits a health plan from requiring a patient to fail the same medication more than once (N.H. Rev. Stat. Ann. § 420-J:7-b).

Vermont similarly prohibits a health plan from requiring that a patient fails the same medication more than once (Vt. Stat. Ann. tit. 8 § 4089i). It also requires managed care organizations to provide adequate notice to members when step therapy requirements change (Vt. Admin. Code 4-5-3:4).
Massachusetts prohibits managed care organizations from imposing step therapy requirements for injectable naltrexone (MassHealth Managed Care Entity Bulletin 1, 2015).

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