

SENATE No. 2433

The Commonwealth of Massachusetts

**In the One Hundred and Ninety-First General Court
(2019-2020)**

An Act relative to step therapy and patient safety.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 118E of the General Laws, as appearing in the 2018 Official
2 Edition, is hereby amended by inserting after section 10M the following section:-

3 Section 10M. (a) As used in this section, the terms “Clinical review criteria” and
4 “utilization review organization” shall have the same meaning as those terms are defined in
5 section 1 of chapter 176O.

6 (b) As used in this section, the terms “Medically necessary” and “Step therapy exception”
7 shall have the same meaning as those terms are defined in section 12A of chapter 176O.

8 (c) “Step therapy protocol” means a protocol, policy, or program that establishes the
9 specific sequence in which prescription drugs for a specified medical condition and medically
10 appropriate for a particular enrollee are covered by MassHealth or a managed care organization
11 or utilization review organization contracted with MassHealth.

12 (d)(1) On or after January 1, 2021, when coverage of a prescription drug for the treatment
13 of any medical condition is restricted for use by MassHealth, or by a managed care organization
14 or utilization review organization contracted with MassHealth to provide coverage to enrollees,
15 through the use of a step therapy protocol, a request for exception from such requirements shall
16 be expeditiously granted if:

17 (A) The required prescription drug is contraindicated or will likely cause an adverse
18 reaction by or physical or mental harm to the enrollee;

19 (B) The required prescription drug is expected to be ineffective based on the known
20 clinical characteristics of the enrollee and the known characteristics of the prescription drug
21 regimen;

22 (C) The enrollee has tried the required prescription drug while covered under
23 MassHealth, a managed care organization or utilization review organization contracted with
24 MassHealth or a previous health insurance or health benefit plan, or another prescription drug in
25 the same pharmacologic class or with the same mechanism of action and such prescription drug
26 was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

27 (D) The required prescription drug is not in the best interest of the enrollee, based on
28 medical necessity.

29 (E) The enrollee is stable on a prescription drug selected by their health care provider for
30 the medical condition under consideration while covered under MassHealth, a managed care
31 organization or utilization review organization contracted with MassHealth or previous health
32 insurance or health benefit plan.

33 (2) Upon the granting of a step therapy exception, MassHealth or a managed care
34 organization or utilization review organization contracted with MassHealth shall authorize
35 coverage for the prescription drug prescribed by the enrollee’s treating health care provider.

36 (3) The MassHealth or a managed care organization or utilization review organization
37 contracted with MassHealth review process for step therapy exception requests shall meet the
38 requirements set forth in 1972(d)(5)(A) of the federal Social Security Act.

39 (e) Nothing in this section shall be construed to prevent:

40 (1) A pharmacist from effecting substitutions of prescription drugs consistent with of
41 section 12D of chapter 112;

42 (2) A health care provider from prescribing a prescription drug that is determined to be
43 medically appropriate.

44 SECTION 2. Chapter 176O of the General Laws, as so appearing, is hereby amended by
45 inserting after section 12 the following 2 sections:-

46 Section 12A. (a) As used in this section, the following words shall, unless the context
47 clearly requires otherwise, have the following meanings:-

48 “Clinical practice guidelines” means a systematically developed statement to assist
49 decision making by health care providers and insureds decisions about appropriate healthcare for
50 specific clinical circumstances and conditions.

51 “Medically necessary” mean health services and supplies that under the applicable
52 standard of care are appropriate: (a) to improve or preserve health, life, or function; (b) to slow

53 the deterioration of health, life, or function; or (c) for the early screening, prevention, evaluation,
54 diagnosis or treatment of a disease, condition, illness or injury.

55 “Step therapy protocol” means a protocol, policy, or program that establishes the specific
56 sequence in which prescription drugs for a specified medical condition and medically appropriate
57 for a particular insured are covered by a carrier.

58 “Step therapy exception” means that a step therapy protocol should be overridden in
59 favor of immediate coverage of the health care provider’s selected prescription drug.

60 (b)(1) Clinical review criteria used to establish a step therapy protocol shall not require an
61 insured to utilize a medication that is not likely to be clinically effective for the prescribed
62 purpose, based on peer-reviewed clinical evidence, in order to obtain coverage for a prescribed
63 medication. Any requirement to utilize a medication other than that prescribed shall be subject to
64 the processes in subsection (c) to ensure an insured’s access to a prescription drug that is likely
65 to be clinically effective for that insured’s individual clinical circumstances.

66 (2) When establishing a step therapy protocol, a carrier or a utilization review
67 organization shall also take into account the needs of atypical patient populations and diagnoses
68 when establishing clinical review criteria.

69 (3) This section shall not be construed to require a carrier or a utilization review
70 organization to set up a new entity to develop clinical review criteria used for step therapy
71 protocols.

72 (c)(1) When coverage of a prescription drug for the treatment of any medical condition is
73 restricted for use by a carrier or a utilization review organization through the use of a step

74 therapy protocol, the insured and prescribing practitioner shall have access to a clear readily
75 accessible and convenient process to request a step therapy exception. A carrier or a utilization
76 review organization may use its existing medical exceptions process to satisfy this requirement.
77 The process shall be made easily accessible on a carrier or a utilization review organization's
78 website.

79 (2) A step therapy exception shall be expeditiously granted if:

80 (A) The prescription drug required under the step therapy protocol is contraindicated or
81 will likely cause an adverse reaction by or physical or mental harm to the insured;

82 (B) The required prescription drug is expected to be ineffective based on the known
83 clinical characteristics of the insured and the known characteristics of the prescription drug
84 regimen;

85 (C) The insured or prescribing clinician has provided documentation to the a carrier or a
86 utilization review organization establishing that the insured has previously tried the required
87 prescription drug, or another prescription drug in the same pharmacologic class or with the same
88 mechanism of action and such prescription drug was discontinued due to lack of efficacy or
89 effectiveness, diminished effect, or an adverse event;

90 (D) The required prescription drug is not in the best interest of the insured, based on
91 medical necessity.

92 (E) The insured or prescribing clinician has provided documentation to a carrier or a
93 utilization review organization establishing that the insured is stable on a prescription drug
94 selected by their health care provider for the medical condition under consideration while on a

95 current or previous health insurance or health benefit plan. In such instances, a carrier or a
96 utilization review organization shall have a continuity of care policy in place to ensure that the
97 insured does not experience any delay in accessing the drug while the exception request is being
98 reviewed.

99 (3) Upon the granting of a step therapy exception, a carrier or a utilization review
100 organization shall authorize coverage for the prescription drug prescribed by the insured's
101 treating health care provider.

102 (4) A carrier or a utilization review organization shall grant or deny a step therapy
103 exception request or an appeal within 72 hours following the receipt of all necessary information
104 to establish the medical necessity of the prescribed treatment. If additional delay would result in
105 significant risk to the insured's health or well-being, a carrier or a utilization review organization
106 shall respond within 24 hours of receipt of all necessary information to establish the medical
107 necessity of the required treatment. Should a response by a carrier or a utilization review
108 organization not be received within the time allotted, the exception or appeal shall be deemed
109 granted.

110 (5) This section shall apply to carriers that provide coverage of a prescription drug
111 pursuant to a policy that meets the definition of a medication step therapy protocol, regardless of
112 whether the policy is described as a step therapy protocol.

113 (d) Any step therapy exception shall be eligible for appeal by an insured.

114 (e) Notwithstanding any law to the contrary, the division shall promulgate any
115 regulations necessary to enforce this section.

116 (f) This section shall apply only to a health benefit plans delivered, issued for delivery, or
117 renewed or after January 1, 2021.

118 (g) A carrier or a utilization review organization shall report to the division annually, in a
119 format prescribed by the division, the following information: (i) the number of step therapy
120 exception requests received; (ii) the type of health care providers or the medical specialties of the
121 health care providers submitting requests; (iii) the number of requests by exception that were
122 initially denied and the reasons for the denials; (iv) the number of requests by exception that
123 were initially approved; and (v) the number of denials by exception that were reversed by
124 internal appeals or an external reviews.

125 Section 12B. There shall be a commission on step therapy protocols within the division.
126 The commission shall consist of: the commissioner of insurance or the commissioner's designee,
127 who shall chair the commission; executive director of the health policy commission or the
128 director's designee; the assistant secretary for MassHealth or the assistant secretary's designee;
129 the executive director of the Center of Health Information and Analysis or the director's
130 designee; a member representing the Massachusetts Public Health Association; and 6 members
131 to be selected by the Governor including: a member representing Blue Cross Blue Shield of
132 Massachusetts, a member representing the Massachusetts Association of Health Plans, two
133 members representing patient advocacy organizations, a member representing an employer
134 organization, a member currently practicing as a licensed physician in Massachusetts, and a
135 member currently practicing as a licensed clinician other than a physician who has prescribing
136 authority under the scope of licensure.

137 The commission on step therapy protocol shall study and assess the implementation of
138 step therapy process reforms enacted pursuant to section 12A and section 10M of chapter 118E.
139 The study shall analyze the impact of step therapy protocols on total medical expenses, health
140 care quality outcomes, premium cost, and out-of-pocket costs to the consumer, and the health
141 care cost benchmark. The study shall also examine any available empirical data on the impact of
142 step therapy protocols on health disparities as relates to outcomes, access and medication
143 adherence in the Commonwealth.

144 The commission shall convene no later than ninety days of the effective date of this act
145 and meet as needed to meet the reporting requirements of this section.

146 The commission on step therapy protocols shall submit to the secretary of health and
147 human services and the joint committee on health care financing, nine months after the effective
148 date of this act and biennially thereafter, a report that includes findings from the commission's
149 review along with recommendations and any suggested legislation to implement those
150 recommendations.