

STATE OF NEW YORK

901--A

2023-2024 Regular Sessions

IN ASSEMBLY

January 11, 2023

Introduced by M. of A. McDONALD, STECK, STIRPE, SANTABARBARA, THIELE, HEVESI, BURDICK, BEEPHAN, NORRIS, K. BROWN, COLTON, BENDETT, GUNTHER, PAULIN, SEAWRIGHT, LEVENBERG, LAVINE, LUNSFORD, ARDILA, COOK, REYES, MEEKS, SAYEGH, JACOBSON, SIMPSON, DAVILA, LUPARDO, SIMON, GALLAHAN, RAGA -- Multi-Sponsored by -- M. of A. EPSTEIN -- read once and referred to the Committee on Insurance -- recommitted to the Committee on Insurance in accordance with Assembly Rule 3, sec. 2 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the insurance law and the public health law, in relation to requiring a utilization review agent to follow certain rules when establishing a step therapy protocol

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Subsection (a) of section 4902 of the insurance law is
2 amended by adding two new paragraphs 15 and 16 to read as follows:

3 (15) When establishing a step therapy protocol, a utilization review
4 agent shall ensure that the protocol cannot:

5 (i) require a prescription drug that has not been approved by the
6 United States Food and Drug Administration for the medical condition
7 being treated and/or is not supported by current evidence-based guide-
8 lines for the medical condition being treated;

9 (ii) require an insured to try and fail on more than two drugs within
10 one therapeutic category before providing coverage to the insured for
11 the prescribed drug;

12 (iii) require the use of a step therapy-required drug for longer than
13 thirty days or a duration of treatment supported by current evidence-
14 based treatment guidelines appropriate to the specific disease state
15 being treated;

16 (iv) be imposed on an insured if a therapeutic equivalent to the
17 prescribed drug is not available, or if the health plan has documenta-

EXPLANATION--Matter in italics (underscored) is new; matter in brackets
[-] is old law to be omitted.

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1 tion that it has covered the drug for the enrollee within the past three
2 hundred sixty-five days;

3 (v) require a newly enrolled insured to repeat step therapy for a
4 prescribed drug where that insured already completed step therapy for
5 that drug under a prior plan, so long as the enrollee or provider
6 submits information demonstrating completion of a step therapy protocol
7 of the prior plan within the past three hundred sixty-five days; and

8 (vi) be imposed on an insured for a prescribed drug that was previous-
9 ly approved for coverage by a plan for a specific medical condition
10 after the insured's plan implements a formulary change or utilization
11 management that impacts the coverage criteria for the prescribed drug
12 until the approved override expires, unless a specifically identified
13 and current evidence-based safety concern exists and a different thera-
14 peutic alternative drug exists.

15 (16) When establishing a step therapy protocol, a utilization review
16 agent shall ensure that the protocol accepts any written or electronic
17 attestation submitted by the insured's health care professional as
18 defined in section four thousand nine hundred of this title stating that
19 a required drug has failed as prima facie evidence that the required
20 drug has failed.

21 § 2. Subsections (c-3) and (g) of section 4903 of the insurance law,
22 subsection (c-3) as added and subsection (g) as amended by chapter 512
23 of the laws of 2016, are amended to read as follows:

24 (c-3) Upon a determination that the step therapy protocol should be
25 overridden, the health plan shall authorize immediate coverage for the
26 prescription drug prescribed by the insured's treating health care
27 professional. Any approval of a step therapy protocol override determi-
28 nation request shall be honored until the lesser of either treatment
29 duration based on current evidence-based treatment guidelines or twelve
30 months following the date of the approval of the request or renewal of
31 the insured's coverage.

32 (g) Failure by the utilization review agent to make a determination
33 within the time periods prescribed in this section shall be deemed to be
34 an adverse determination subject to appeal pursuant to section four
35 thousand nine hundred four of this title, provided, however, that fail-
36 ure to meet such time periods for a step therapy protocol as defined in
37 subsection (g-9) of section forty-nine hundred of this title or a step
38 therapy protocol override determination pursuant to subsections (c-1),
39 (c-2) and (c-3) of this section shall be deemed to be an override of the
40 step therapy protocol. A utilization review agent's failure to comply
41 with any of the step therapy protocol requirements required in
42 subsections fifteen and sixteen of section four thousand nine hundred
43 two of this title shall be considered a basis for granting an override
44 of the step therapy protocol, absent fraud.

45 § 3. Section 4902 of the public health law is amended by adding two
46 new subdivisions 5 and 6 to read as follows:

47 5. When establishing a step therapy protocol, a utilization review
48 agent shall ensure that the protocol cannot:

49 (a) require a prescription drug that has not been approved by the
50 United States Food and Drug Administration and/or is not supported by
51 current evidence-based guidelines for the medical condition being treat-
52 ed;

53 (b) require an enrollee to try and fail on more than two drugs within
54 one therapeutic category before providing coverage to the insured for
55 the prescribed drug;

1 (c) require the use of a step therapy-required drug for longer than
2 thirty days or a duration of treatment supported by current evidence-
3 based treatment guidelines appropriate to the specific disease state
4 being treated;

5 (d) be imposed on an enrollee if a therapeutic equivalent to the
6 prescribed drug is not available; or if the health plan has documenta-
7 tion that it has covered the drug for the enrollee within the past three
8 hundred sixty-five days;

9 (e) require a newly enrolled enrollee to repeat step therapy for a
10 prescribed drug where that enrollee already completed step therapy for
11 that drug under a prior plan, so long as the enrollee or provider submit
12 information demonstrating completion of a step therapy protocol of the
13 prior plan within the past three hundred sixty-five days; and

14 (f) be imposed on an enrollee for a prescribed drug that was previous-
15 ly approved for coverage by a plan for a specific medical condition
16 after the enrollee's plan implements a formulary or utilization manage-
17 ment change that impacts the coverage criteria for the prescribed drug
18 until the approved override expires, unless a specifically identified
19 and evidence-based safety concern exists and a different therapeutic
20 alternative drug exists.

21 6. When establishing a step therapy protocol, a utilization review
22 agent shall ensure that the protocol accepts any written or electronic
23 attestation submitted by the enrollee's health care professional as
24 defined in section forty-nine hundred of this title stating that a
25 required drug has failed as prima facie evidence that the required drug
26 has failed.

27 § 4. Subdivisions 3-c and 7 of section 4903 of the public health law,
28 subdivision 3-c as added and subdivision 7 as amended by chapter 512 of
29 the laws of 2016, are amended to read as follows:

30 3-c. Upon a determination that the step therapy protocol should be
31 overridden, the health plan shall authorize immediate coverage for the
32 prescription drug or drugs prescribed by the enrollee's treating health
33 care professional. Any approval of a step therapy protocol override
34 determination request shall be honored until the lesser of either treat-
35 ment duration based on current evidence-based treatment guidelines or
36 twelve months following the date of the approval of the request or
37 renewal of the enrollee's coverage.

38 7. Failure by the utilization review agent to make a determination
39 within the time periods prescribed in this section shall be deemed to be
40 an adverse determination subject to appeal pursuant to section forty-
41 nine hundred four of this title, provided, however, that failure to meet
42 such time periods for a step therapy protocol as defined in subdivision
43 seven-f-three of section forty-nine hundred of this title or a step
44 therapy protocol override determination pursuant to subdivisions
45 three-a, three-b and three-c of this section shall be deemed to be an
46 override of the step therapy protocol. A utilization review agent's
47 failure to comply with any of the step therapy protocol requirements
48 required in subdivisions five and six of section forty-nine hundred two
49 of this title shall be considered a basis for granting an override of
50 the step therapy protocol, absent fraud.

51 § 5. This act shall take effect on the one hundred twentieth day after
52 it shall have become a law.