

2020 -- S 2243

=====  
LC004077  
=====

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2020

—————  
A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES --  
STEP THERAPY PROTOCOLS

Introduced By: Senators Gallo, Conley, Lombardo, and Goodwin

Date Introduced: February 04, 2020

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness  
2 Insurance Policies" is hereby amended by adding thereto the following section:

3 **27-18-85. Step therapy protocol.**

4 (a) As used in this section the following words shall, unless the context clearly requires  
5 otherwise, have the following meanings:

6 (1) "Clinical practice guidelines" means a systematically developed statement to assist  
7 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

8 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,  
9 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review  
10 organization to determine the medical necessity and appropriateness of health care services.

11 (3) "Step therapy exception" means a process that provides that a step therapy protocol  
12 should be overridden in favor of immediate coverage of the health care provider's selected  
13 prescription drug.

14 (4) "Step therapy protocol" means a protocol or program that establishes the specific  
15 sequence in which prescription drugs for a specified medical condition that are medically  
16 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including  
17 self-administered and physician-administered drugs, are covered by an insurer or health plan.

18 (5) "Utilization review organization" means an entity that conducts utilization review,

1 other than a health carrier performing utilization review for its own health benefit plans.

2 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or  
3 renewed within the state that provides coverage for prescription drugs and uses step therapy  
4 protocols shall have the following requirements and restrictions:

5 (1) Clinical review criteria used to establish step therapy protocols shall be based on  
6 clinical practice guidelines:

7 (i) Independently developed by a multidisciplinary panel with expertise in the medical  
8 condition, or conditions, for which coverage decisions said criteria will be applied; and

9 (ii) That recommend drugs be taken in the specific sequence required by the step therapy  
10 protocol.

11 (c) When coverage of medications for the treatment of any medical condition are  
12 restricted for use by an insurer, health plan, or utilization review organization via a step therapy  
13 protocol, the patient and prescribing practitioner shall have access to a clear and convenient  
14 process to request a step therapy exception. An insurer, health plan, or utilization review  
15 organization shall use its existing medical exceptions process to satisfy this requirement. The  
16 process shall be disclosed to the patient and health care providers, including documenting and  
17 making easily accessible on the insurer's, health plan's or utilization review organization's  
18 website.

19 (d) A step therapy override exception shall be expeditiously granted if:

20 (1) The required drug is contraindicated or will likely cause an adverse reaction, or  
21 physical or mental harm to the patient;

22 (2) The required prescription drug is expected to be ineffective based on the known  
23 clinical characteristics of the patient and the known characteristics of the prescription drug  
24 regimen;

25 (3) The enrollee has tried the step therapy-required drug while under their current health  
26 plan, or another drug in the same pharmacologic class or with the same mechanism of action and  
27 such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an  
28 adverse event;

29 (4) The patient is stable on a drug recommended by their health care provider for the  
30 medical condition under consideration while on a current or previous health insurance or health  
31 benefit plan and no generic substitution is available. This subsection shall not be construed to  
32 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override  
33 exception.

34 (e) Upon the granting of a step therapy override exception request, the insurer, health

1 plan, utilization review organization, or other entity shall authorize coverage for the drug  
2 prescribed by the enrollee's treating health care provider, provided such drug is a covered drug  
3 under such terms of policy or contract.

4 (f) The insurer, health plan, or utilization review organization shall grant or deny a step  
5 therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where  
6 exigent circumstances exist an insurer, health plan, or utilization review organization shall grant  
7 or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt.  
8 Should a grant or denial by an insurer, health plan, or utilization review organization not be  
9 received within the time allotted, the exception or appeal shall be deemed granted.

10 (g) Any step therapy exception as defined by this subsection shall be eligible for appeal  
11 by an insured.

12 (h) This section shall not be construed to prevent:

13 (1) An insurer, health plan, or utilization review organization from requiring an enrollee  
14 to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
15 branded drug;

16 (2) A health care provider from prescribing a drug they determine is medically  
17 appropriate.

18 (i) The health insurance commissioner may promulgate such rules and regulations,  
19 including rules and regulations under chapter 18.9 of title 27, the benefit determination and  
20 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient  
21 administration and enforcement of this section entitled "step therapy protocol", as well as to  
22 effectuate the coordination of the efficient administration and enforcement of this section with the  
23 act.

24 SECTION 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service  
25 Corporations" is hereby amended by adding thereto the following section:

26 **27-19-77. Step therapy protocol.**

27 (a) As used in this section the following words shall, unless the context clearly requires  
28 otherwise, have the following meanings:

29 (1) "Clinical practice guidelines" means a systematically developed statement to assist  
30 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

31 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,  
32 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review  
33 organization to determine the medical necessity and appropriateness of health care services.

34 (3) "Step therapy exception" means a process that provides that a step therapy protocol

1 should be overridden in favor of immediate coverage of the health care provider's selected  
2 prescription drug.

3 (4) "Step therapy protocol" means a protocol or program that establishes the specific  
4 sequence in which prescription drugs for a specified medical condition that are medically  
5 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including  
6 self-administered and physician-administered drugs, are covered by an insurer or health plan.

7 (5) "Utilization review organization" means an entity that conducts utilization review,  
8 other than a health carrier performing utilization review for its own health benefit plans.

9 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or  
10 renewed within the state that provides coverage for prescription drugs and uses step therapy  
11 protocols shall have the following requirements and restrictions:

12 (1) Clinical review criteria used to establish step therapy protocols shall be based on  
13 clinical practice guidelines:

14 (i) Independently developed by a multidisciplinary panel with expertise in the medical  
15 condition, or conditions, for which coverage decisions said criteria will be applied; and

16 (ii) That recommend drugs be taken in the specific sequence required by the step therapy  
17 protocol.

18 (c) When coverage of medications for the treatment of any medical condition are  
19 restricted for use by an insurer, health plan, or utilization review organization via a step therapy  
20 protocol, the patient and prescribing practitioner shall have access to a clear and convenient  
21 process to request a step therapy exception. An insurer, health plan, or utilization review  
22 organization shall use its existing medical exceptions process to satisfy this requirement. The  
23 process shall be disclosed to the patient and health care providers, including documenting and  
24 making easily accessible on the insurer's, health plan's or utilization review organization's  
25 website.

26 (d) A step therapy override exception shall be expeditiously granted if:

27 (1) The required drug is contraindicated or will likely cause an adverse reaction, or  
28 physical or mental harm to the patient;

29 (2) The required prescription drug is expected to be ineffective based on the known  
30 clinical characteristics of the patient and the known characteristics of the prescription drug  
31 regimen;

32 (3) The enrollee has tried the step therapy-required drug while under their current health  
33 plan, or another drug in the same pharmacologic class or with the same mechanism of action and  
34 such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an

1 adverse event:

2 (4) The patient is stable on a drug recommended by their health care provider for the  
3 medical condition under consideration while on a current or previous health insurance or health  
4 benefit plan and no generic substitution is available. This subsection shall not be construed to  
5 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override  
6 exception.

7 (e) Upon the granting of a step therapy override exception request, the insurer, health  
8 plan, utilization review organization, or other entity shall authorize coverage for the drug  
9 prescribed by the enrollee's treating health care provider, provided such drug is a covered drug  
10 under such terms of policy or contract.

11 (f) The insurer, health plan, or utilization review organization shall grant or deny a step  
12 therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where  
13 exigent circumstances exist an insurer, health plan, or utilization review organization shall grant  
14 or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt.  
15 Should a grant or denial by an insurer, health plan, or utilization review organization not be  
16 received within the time allotted, the exception or appeal shall be deemed granted.

17 (g) Any step therapy exception as defined by this subsection shall be eligible for appeal  
18 by an insured.

19 (h) This section shall not be construed to prevent:

20 (1) An insurer, health plan, or utilization review organization from requiring an enrollee  
21 to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
22 branded drug;

23 (2) A health care provider from prescribing a drug they determine is medically  
24 appropriate.

25 (i) The health insurance commissioner may promulgate such rules and regulations,  
26 including rules and regulations under chapter 18.9 of title 27, the benefit determination and  
27 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient  
28 administration and enforcement of this section entitled "step therapy protocol", as well as to  
29 effectuate the coordination of the efficient administration and enforcement of this section with the  
30 act.

31 SECTION 3. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service  
32 Corporations" is hereby amended by adding thereto the following section:

33 **27-20-73. Step therapy protocol.**

34 (a) As used in this section the following words shall, unless the context clearly requires

1 otherwise, have the following meanings:

2 (1) "Clinical practice guidelines" means a systematically developed statement to assist  
3 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

4 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,  
5 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review  
6 organization to determine the medical necessity and appropriateness of health care services.

7 (3) "Step therapy exception" means a process that provides that a step therapy protocol  
8 should be overridden in favor of immediate coverage of the health care provider's selected  
9 prescription drug.

10 (4) "Step therapy protocol" means a protocol or program that establishes the specific  
11 sequence in which prescription drugs for a specified medical condition that are medically  
12 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including  
13 self-administered and physician-administered drugs, are covered by an insurer or health plan.

14 (5) "Utilization review organization" means an entity that conducts utilization review,  
15 other than a health carrier performing utilization review for its own health benefit plans.

16 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or  
17 renewed within the state that provides coverage for prescription drugs and uses step therapy  
18 protocols shall have the following requirements and restrictions:

19 (1) Clinical review criteria used to establish step therapy protocols shall be based on  
20 clinical practice guidelines:

21 (i) Independently developed by a multidisciplinary panel with expertise in the medical  
22 condition, or conditions, for which coverage decisions said criteria will be applied; and

23 (ii) That recommend drugs be taken in the specific sequence required by the step therapy  
24 protocol.

25 (c) When coverage of medications for the treatment of any medical condition are  
26 restricted for use by an insurer, health plan, or utilization review organization via a step therapy  
27 protocol, the patient and prescribing practitioner shall have access to a clear and convenient  
28 process to request a step therapy exception. An insurer, health plan, or utilization review  
29 organization shall use its existing medical exceptions process to satisfy this requirement. The  
30 process shall be disclosed to the patient and health care providers, including documenting and  
31 making easily accessible on the insurer's, health plan's or utilization review organization's  
32 website.

33 (d) A step therapy override exception shall be expeditiously granted if:

34 (1) The required drug is contraindicated or will likely cause an adverse reaction, or

1 physical or mental harm to the patient;

2 (2) The required prescription drug is expected to be ineffective based on the known  
3 clinical characteristics of the patient and the known characteristics of the prescription drug  
4 regimen;

5 (3) The enrollee has tried the step therapy-required drug while under their current health  
6 plan, or another drug in the same pharmacologic class or with the same mechanism of action and  
7 such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an  
8 adverse event;

9 (4) The patient is stable on a drug recommended by their health care provider for the  
10 medical condition under consideration while on a current or previous health insurance or health  
11 benefit plan and no generic substitution is available. This subsection shall not be construed to  
12 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override  
13 exception.

14 (e) Upon the granting of a step therapy override exception request, the insurer, health  
15 plan, utilization review organization, or other entity shall authorize coverage for the drug  
16 prescribed by the enrollee's treating health care provider, provided such drug is a covered drug  
17 under such terms of policy or contract.

18 (f) The insurer, health plan, or utilization review organization shall grant or deny a step  
19 therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where  
20 exigent circumstances exist an insurer, health plan, or utilization review organization shall grant  
21 or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt.  
22 Should a grant or denial by an insurer, health plan, or utilization review organization not be  
23 received within the time allotted, the exception or appeal shall be deemed granted.

24 (g) Any step therapy exception as defined by this subsection shall be eligible for appeal  
25 by an insured.

26 (h) This section shall not be construed to prevent:

27 (1) An insurer, health plan, or utilization review organization from requiring an enrollee  
28 to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
29 branded drug;

30 (2) A health care provider from prescribing a drug they determine is medically  
31 appropriate.

32 (i) The health insurance commissioner may promulgate such rules and regulations,  
33 including rules and regulations under chapter 18.9 of title 27, the benefit determination and  
34 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient

1 administration and enforcement of this section entitled "step therapy protocol", as well as to  
2 effectuate the coordination of the efficient administration and enforcement of this section with the  
3 act.

4 SECTION 4. Chapter 27-41 of the General Laws entitled "Health Maintenance  
5 Organizations" is hereby amended by adding thereto the following section:

6 **27-41-90. Step therapy protocol.**

7 (a) As used in this section the following words shall, unless the context clearly requires  
8 otherwise, have the following meanings:

9 (1) "Clinical practice guidelines" means a systematically developed statement to assist  
10 practitioner and patient decisions about appropriate health care for specific clinical circumstances.

11 (2) "Clinical review criteria" means the written screening procedures, decision abstracts,  
12 clinical protocols and practice guidelines used by an insurer, health plan, or utilization review  
13 organization to determine the medical necessity and appropriateness of health care services.

14 (3) "Step therapy exception" means a process that provides that a step therapy protocol  
15 should be overridden in favor of immediate coverage of the health care provider's selected  
16 prescription drug.

17 (4) "Step therapy protocol" means a protocol or program that establishes the specific  
18 sequence in which prescription drugs for a specified medical condition that are medically  
19 appropriate for a particular patient and are covered as a pharmacy or medical benefit, including  
20 self-administered and physician-administered drugs, are covered by an insurer or health plan.

21 (5) "Utilization review organization" means an entity that conducts utilization review,  
22 other than a health carrier performing utilization review for its own health benefit plans.

23 (b) Any policy, contract, agreement, plan or certificate of insurance issued, delivered or  
24 renewed within the state that provides coverage for prescription drugs and uses step therapy  
25 protocols shall have the following requirements and restrictions:

26 (1) Clinical review criteria used to establish step therapy protocols shall be based on  
27 clinical practice guidelines:

28 (i) Independently developed by a multidisciplinary panel with expertise in the medical  
29 condition, or conditions, for which coverage decisions said criteria will be applied; and

30 (ii) That recommend drugs be taken in the specific sequence required by the step therapy  
31 protocol.

32 (c) When coverage of medications for the treatment of any medical condition are  
33 restricted for use by an insurer, health plan, or utilization review organization via a step therapy  
34 protocol, the patient and prescribing practitioner shall have access to a clear and convenient



1 process to request a step therapy exception. An insurer, health plan, or utilization review  
2 organization shall use its existing medical exceptions process to satisfy this requirement. The  
3 process shall be disclosed to the patient and health care providers, including documenting and  
4 making easily accessible on the insurer's, health plan's or utilization review organization's  
5 website.

6 (d) A step therapy override exception shall be expeditiously granted if:

7 (1) The required drug is contraindicated or will likely cause an adverse reaction, or  
8 physical or mental harm to the patient;

9 (2) The required prescription drug is expected to be ineffective based on the known  
10 clinical characteristics of the patient and the known characteristics of the prescription drug  
11 regimen;

12 (3) The enrollee has tried the step therapy-required drug while under their current health  
13 plan, or another drug in the same pharmacologic class or with the same mechanism of action and  
14 such drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an  
15 adverse event;

16 (4) The patient is stable on a drug recommended by their health care provider for the  
17 medical condition under consideration while on a current or previous health insurance or health  
18 benefit plan and no generic substitution is available. This subsection shall not be construed to  
19 allow the use of a pharmaceutical sample to meet the requirements for a step therapy override  
20 exception.

21 (e) Upon the granting of a step therapy override exception request, the insurer, health  
22 plan, utilization review organization, or other entity shall authorize coverage for the drug  
23 prescribed by the enrollee's treating health care provider, provided such drug is a covered drug  
24 under such terms of policy or contract.

25 (f) The insurer, health plan, or utilization review organization shall grant or deny a step  
26 therapy exception request or an appeal within seventy-two (72) hours of receipt. In cases where  
27 exigent circumstances exist an insurer, health plan, or utilization review organization shall grant  
28 or deny a step therapy exception request or an appeal within twenty-four (24) hours of receipt.  
29 Should a grant or denial by an insurer, health plan, or utilization review organization not be  
30 received within the time allotted, the exception or appeal shall be deemed granted.

31 (g) Any step therapy exception as defined by this subsection shall be eligible for appeal  
32 by an insured.

33 (h) This section shall not be construed to prevent:

34 (1) An insurer, health plan, or utilization review organization from requiring an enrollee

1 to try an AB-rated generic equivalent prior to providing reimbursement for the equivalent  
2 branded drug;

3 (2) A health care provider from prescribing a drug they determine is medically  
4 appropriate.

5 (i) The health insurance commissioner may promulgate such rules and regulations,  
6 including rules and regulations under chapter 18.9 of title 27, the benefit determination and  
7 utilization review act, as are necessary and proper to effectuate the purpose and for the efficient  
8 administration and enforcement of this section entitled "step therapy protocol", as well as to  
9 effectuate the coordination of the efficient administration and enforcement of this section with the  
10 act.

11 SECTION 5. This act shall take effect upon passage and shall apply only to health  
12 insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1,  
13 2021.

=====  
LC004077  
=====

EXPLANATION  
BY THE LEGISLATIVE COUNCIL  
OF

A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES --  
STEP THERAPY PROTOCOLS

\*\*\*

1           This act would require health insurers, nonprofit hospital service corporations, nonprofit  
2   medical service corporations and health maintenance organizations that issue policies that provide  
3   coverage for prescription drugs and use step therapy protocols, to base step therapy protocols on  
4   appropriate clinical practice guidelines or published peer review data developed by independent  
5   experts with knowledge of the condition or conditions under consideration; that patients be  
6   exempt from step therapy protocols when inappropriate; and that patients have access to a fair,  
7   transparent and independent process for requesting an exception to a step therapy protocol when  
8   the patient's physician deems appropriate.

9           This act would take effect upon passage and shall apply only to health insurance and  
10   health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2021.

=====  
LC004077  
=====