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: Representatives Serpa, Blazejewski, Chippendale, Jackson, and Bennett

Date Introduced: February 07, 2020

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

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


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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27-19-77. Step therapy protocol.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27-20-73. Step therapy protocol.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Organizations" is hereby amended by adding thereto the following section:

27-41-90. Step therapy protocol.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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