

PROPOSED RULE 107
REGULATION OF MEDICATION STEP THERAPY PROTOCOLS

1. PURPOSE
2. AUTHORITY
3. APPLICABILITY
4. DEFINITIONS
5. DEVELOPMENT OF CLINICAL REVIEW CRITERIA
6. ACCESS TO CLINICAL REVIEW CRITERIA
7. ACCESS TO STEP THERAPY PROTOCOL EXCEPTION PROCESS
8. RESPONSE TO REQUESTS FOR STEP THERAPY PROTOCOL EXCEPTIONS
9. APPEALING A DENIAL OF A REQUEST FOR EXCEPTION
10. ENFORCEMENT
11. EFFECTIVE DATE

SECTION 1. PURPOSE

This Rule implements Act 97 of 2021 and Act 645 of 2021, which amends a definition within Act 97. Act 97 requires healthcare insurers to base medication step therapy protocols on appropriate clinical practice guidelines or peer-reviewed data developed by independent experts with knowledge of the condition or conditions under consideration. Act 97 also ensures that patients have access to a fair, transparent, and independent process for requesting a step therapy protocol exception when the patient's physician deems it appropriate.

SECTION 2. AUTHORITY

This Rule is issued pursuant to the authority granted the Arkansas Insurance Commissioner ("Commissioner") by Act 97 of 2021, codified at Ark. Code Ann. § 23-79-2101 et seq., which provides the Commissioner with authority necessary to promulgate rules to implement Section 7 of Act 97 of 2021.

SECTION 3. APPLICABILITY

This subchapter applies to a group health benefit plan or health insurance coverage offered in connection with a group health plan that provides coverage of a prescription drug under a policy that meets the definition of a medication step therapy protocol whether or not the policy is described as a step therapy protocol.

SECTION 4. DEFINITIONS

(1) "Clinical practice guidelines" means a systematically developed statement derived from peer-reviewed published medical literature, evidence-based research, and widely accepted medical practice to assist decision-making by healthcare providers and patients about appropriate healthcare for specific clinical circumstances and conditions.

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

(3) "Generic equivalent" means a drug rated "A" or "B" by the United States Preventive Taskforce that is pharmaceutically and therapeutically equivalent to the drug prescribed.

(4) (a) "Health benefit plan" means an individual, blanket, or any group plan, policy, or contract for healthcare services issued, renewed, or extended in this state by a healthcare insurer, health maintenance organization, hospital medical service corporation, or self-insured governmental or church plan in this state.

(b) "Health benefit plan" includes:

(1) Indemnity and managed care plans;

(2) Plans providing health benefits to state and public school employees under Ark. Code Ann. § 21-5-401 et seq.; and

(3) Individual qualified health insurance plans under Ark. Code Ann. § 23-61-1001 et seq.

(c) "Health benefit plan" does not include:

(1) A disability income plan;

(2) A credit insurance plan;

(3) Insurance coverage issued as a supplement to liability insurance;

(4) Medical payments under an automobile or homeowner insurance plan;

(5) A health benefit plan provided under Arkansas Constitution, Article 5, § 32, the Workers' Compensation Law, Ark. Code Ann. § 11-9-101 et seq., and the Public Employee Workers' Compensation Act, Ark. Code Ann. § 21-5-601 et seq.;

(6) A plan that provides only indemnity for hospital confinement;

(7) An accident-only plan;

(8) A specified disease plan;

(9) A plan that provides only dental benefits or eye and vision care benefits; or

(10) A program or plan authorized under 42 U.S.C. § 1396a et seq., as it existed on January 1, 2021, as approved by the United States Secretary of Health and Human Services, excluding individual qualified health plans under Ark. Code Ann. § 23-61-1001 et seq.

(5) (a) "Healthcare insurer" means an insurance company, a hospital medical service corporation, or a health maintenance organization that issues or delivers health benefit plans in this state and is subject to any of the following laws:

(1) The insurance laws of this state;

(2) Ark. Code Ann. § 23-75-101 et seq., pertaining to hospital and medical service corporations; or

(3) Ark. Code Ann. § 23-76-101 et seq., pertaining to health maintenance organizations.

(b) "Healthcare insurer" does not include an entity that provides only dental benefits or eye and vision care benefits.

(6) "Interchangeable biological product" means a biological product that is interchangeable, as "interchangeable" is defined by 42 U.S.C. § 262(i)(3), as it existed on January 1, 2021.

(7) "Medically necessary" means healthcare services and supplies that, under the applicable standard of care, are appropriate:

(a) To improve or preserve health, life, or function;

(b) To slow the deterioration of health, life, or function; or

(c) For the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury.

(8) "Step therapy protocol" means a protocol, policy, or program that establishes the specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a patient are covered by a healthcare insurer or health benefit plan.

(9) "Step therapy protocol exception" means that a step therapy protocol is overridden in favor of immediate coverage of the healthcare provider's selected prescription drug.

(10)(a) "Utilization review organization" means an individual or entity that performs step therapy for at least one (1) of the following:

(1) A healthcare insurer;

(2) A preferred provider organization or health maintenance organization;
or

(3) Any other individual or entity that provides, offers to provide, or administers hospital, outpatient, medical, or other health benefits to a person treated by a healthcare provider in this state under a policy, health benefit plan, or contract.

(b) A healthcare insurer is a utilization review entity if the healthcare insurer performs step therapy.

(c) "Utilization review organization" does not include an insurer of automobile, homeowner, or casualty and commercial liability insurance or the insurer's employees, agents, or contractors.

SECTION 5. DEVELOPMENT OF CLINICAL REVIEW CRITERIA

(a) Health insurers shall base clinical review criteria used to establish step therapy protocols on appropriate clinical practice guidelines or peer-reviewed published medical literature.

(b) For step therapy protocols based on clinical practice guidelines, such guidelines shall be:

(1) Developed and endorsed by a multidisciplinary panel of experts who manage conflicts of interest among the members of the writing and review groups by:

(A) Requiring members to disclose any potential conflicts of interest with entities, including healthcare insurers, health benefit plans, and pharmaceutical manufacturers, and to recuse from voting if the member has a conflict of interest;

(B) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

(C) Offering opportunities for public review and comments;

(2) Based on high-quality studies, research, and medical practices;

(3) Created by an explicit and transparent process that:

(A) Minimizes biases and conflicts of interest;

(B) Explains the relationship between treatment options and outcomes;

(C) Rates the quality of the evidence supporting recommendations; and

(D) Considers relevant patient subgroups and preferences; and

(4) Continually updated through a review of new evidence, research, and newly developed treatments.

(c) For step therapy protocols based on peer-reviewed published medical literature, such materials, when applicable, shall be:

(1) Based on high-quality studies, research, and medical practices; and

(2) Created by an explicit and transparent process that:

(A) Minimizes biases and conflicts of interest;

(B) Explains the relationship between treatment options and outcomes;

(C) Rates the quality of the evidence supporting recommendations; and

(D) Considers relevant patient subgroups and preferences.

(d) If establishing a step therapy protocol, a utilization review agent shall take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(e) Healthcare insurers, health benefit plans, or the state are not required to set up a new entity to develop critical review criteria used for step therapy protocols.

SECTION 6. ACCESS TO CLINICAL REVIEW CRITERIA

(a) Upon written request, a healthcare insurer, pharmacy benefit manager, or utilization review organization shall provide all specific written clinical review criteria relating to the particular condition or disease, including clinical review criteria relating to a step therapy protocol override determination; and

(b) A healthcare insurer, pharmacy benefit manager, or utilization review organization shall make clinical review criteria and other clinical information available on its website and to a healthcare professional on behalf of an insured upon written request.

SECTION 7. ACCESS TO STEP THERAPY PROTOCOL EXCEPTION PROCESS

(a) If coverage of a prescription drug for the treatment of any medical condition is restricted for use by a healthcare insurer, health benefit plan, or utilization review organization through the use of a step therapy protocol, a patient and prescribing healthcare provider shall have access to a clear, readily accessible, and convenient process to request a step therapy protocol exception.

(b)(1) A healthcare insurer, health benefit plan, or utilization review organization may use its existing medical exceptions process to satisfy the requirement under subsection (a) of this section.

(2) The existing medical exceptions process shall be easily accessible on the website of the healthcare insurer, health benefit plan, or utilization review organization.

(3) Upon request, a healthcare insurer, health benefit plan, or utilization review organization shall disclose to a prescribing healthcare provider all rules and clinical review criteria related to the step therapy protocol, including without limitation the specific information and documentation that is required to be submitted by a prescribing healthcare provider or patient to the healthcare insurer, health benefit plan, or utilization review organization to be considered a complete step therapy protocol exception request.

SECTION 8. RESPONSE TO REQUESTS FOR STEP THERAPY PROTOCOL EXCEPTIONS

(a) A healthcare insurer, health benefit plan, or utilization review organization shall expeditiously grant a step therapy protocol exception if:

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

(2) A 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) A patient has tried the required prescription drug while under the patient's current or previous health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

(4) A required prescription drug is not in the best interest of the patient, based on medical necessity; or

(5) A patient is stable on a prescription drug selected by the patient's healthcare provider for the medical condition under consideration while on a current or previous health benefit plan.

(b)(1) The healthcare insurer, health benefit plan, or utilization review organization shall grant or deny a request for a step therapy protocol exception within seventy-two (72) hours of receiving the request.

(2) However, in cases in which exigent circumstances exist, the healthcare insurer, health benefit plan, or utilization review organization shall grant or deny the request within twenty-four (24) hours of receiving the request.

(c) If a response by a healthcare insurer, health benefit plan, or utilization review organization is not received within the time allotted under this section, the request for a step therapy protocol exception shall be deemed granted.

(d)(1) If a request for a step therapy protocol exception is incomplete or additional clinically relevant information is required, a healthcare insurer, health benefit plan, or utilization review organization shall notify the prescribing healthcare provider within seventy-two (72) hours of submission, or twenty-four (24) hours in exigent circumstances, of the additional or clinically relevant information that is required in order to approve or deny the step therapy protocol exception request.

(2) Once the requested information is submitted, the applicable time period to grant or deny a step therapy protocol exception request shall apply.

(3) If a determination or notice of incomplete or clinically relevant information by a healthcare insurer, health benefit plan, or utilization review organization is not received by the prescribing healthcare provider within the time allotted, the step therapy protocol exception shall be deemed granted.

(e) Upon the granting of a step therapy protocol exception, a healthcare insurer, health benefit plan, or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating healthcare provider.

(f) In the event of a denial, a healthcare insurer, health benefit plan, or utilization review organization shall inform the patient of a potential appeal process.

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

(1) A healthcare insurer, a health benefit plan, or a utilization review organization from requiring:

(A) A patient to try a generic equivalent or interchangeable biological product unless such a requirement meets Ark. Code Ann. § 23-79-2104(b) pursuant to a step therapy protocol exception request submitted under Ark. Code Ann. § 23-79-2104(b); or

(B) A pharmacist to effect substitutions of prescription drugs consistent with Ark. Code Ann. § 17-92-503; or

(2) A healthcare provider from prescribing a prescription drug that is determined to be medically necessary.

SECTION 9. APPEALING A DENIAL OF A REQUEST FOR EXCEPTION

(a)(1) A patient covered by a healthcare insurer under a health benefit plan may appeal the denial of a request for a step therapy protocol exception.

(2) The health benefit plan shall grant or deny the appeal within seventy-two (72) hours of receiving the appeal.

(3) In cases in which exigent circumstances exist, the health benefit plan shall grant or deny the appeal within twenty-four (24) hours of receiving the appeal.

(b) If a response by a healthcare insurer, health benefit plan, or utilization review organization is not received within the time allotted under this section, the appeal of a denial of a request shall be deemed granted.

(c)(1) If an appeal is incomplete or additional clinically relevant information is required, a healthcare insurer, health benefit plan, or utilization review organization shall notify the prescribing healthcare provider within seventy-two (72) hours of submission, or twenty-four (24) hours in exigent circumstances, of the additional or clinically relevant information that is required in order to approve or deny the appeal.

(2) Once the requested information is submitted, the applicable time period to grant or deny an appeal shall apply.

(3) If a determination or notice of incomplete or clinically relevant information by a healthcare insurer, health benefit plan, or utilization review organization is not received by the prescribing healthcare provider within the time allotted, the appeal shall be deemed granted.

SECTION 10. ENFORCEMENT

Violations of this Rule shall constitute an unfair or deceptive act under Ark. Code Ann. § 23-66-206. Therefore, the penalties, actions or orders, including but not limited to monetary fines, suspension, or revocation of license, as authorized under Ark. Code Ann. §§ 23-66-209 and 23-66-210, shall apply to violations of this Rule.

SECTION 11. EFFECTIVE DATE

The effective date of this Rule is November 1, 2021.

ALAN MCCLAIN
INSURANCE COMMISSIONER

DATE

1 State of Arkansas *As Engrossed: S1/25/21 S1/28/21*
2 93rd General Assembly **A Bill**
3 Regular Session, 2021

SENATE BILL 99

4
5 By: Senators Bledsoe, D. Wallace, *Irvin*
6 By: Representatives Vaught, *Lundstrum*

7
8 **For An Act To Be Entitled**

9 AN ACT TO REGULATE STEP THERAPY PROTOCOLS; AND FOR
10 OTHER PURPOSES.

11
12
13 **Subtitle**

14 TO REGULATE STEP THERAPY PROTOCOLS.

15
16
17 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

18
19 SECTION 1. Arkansas Code § 23-61-804(a)(3)(B)(iii), concerning the
20 duties of the Arkansas Health Insurance Marketplace, is repealed.

21 ~~(iii) Step therapy requirements;~~

22
23 SECTION 2. Arkansas Code Title 23, Chapter 79, is amended to add an
24 additional subchapter to read as follows:

25 Subchapter 21 – Regulation of Step Therapy Protocols

26
27 23-79-2101. Legislative findings and intent.

28 (a) The General Assembly finds that:

29 (1) Health benefit plans are increasingly making use of step
30 therapy protocols under which patients are required to try one (1) or more
31 prescription drugs before coverage is provided for a drug selected by the
32 patient's healthcare provider;

33 (2) Such step therapy protocols, if the step therapy protocols
34 are based on well-developed scientific standards and administered in a
35 flexible manner that takes into account the individual needs of a patient,
36 can play an important role in controlling healthcare costs; and



1 "(3) Without uniform policies in the state for step therapy
2 protocols, a patient may not receive the equivalent or most appropriate
3 treatment.

4 (b) It is the intent of the General Assembly that:

5 (1) To require healthcare insurers to base step therapy
6 protocols on appropriate clinical practice guidelines or published peer-
7 reviewed data developed by independent experts with knowledge of the
8 condition or conditions under consideration is a matter of public interest;
9 and

10 (2) Patients have access to a fair, transparent, and independent
11 process for requesting a step therapy protocol exception when the patient's
12 physician deems it appropriate.

13
14 23-79-2102. Definitions.

15 As used in this subchapter:

16 (1) "Clinical practice guidelines" means a systematically
17 developed statement derived from peer-reviewed published medical literature,
18 evidence-based research, and widely accepted medical practice to assist
19 decision-making by healthcare providers and patients about appropriate
20 healthcare for specific clinical circumstances and conditions;

21 (2) "Clinical review criteria" means the written screening
22 procedures, decision abstracts, clinical protocols, and clinical practice
23 guidelines used by a healthcare insurer, health benefit plan, or utilization
24 review organization to determine the medical necessity and appropriateness of
25 healthcare services;

26 (3) "Generic equivalent" means an AB-rated drug that is
27 pharmaceutically and therapeutically equivalent to the drug prescribed;

28 (4)(A) "Health benefit plan" means an individual, blanket, or
29 any group plan, policy, or contract for healthcare services issued, renewed,
30 or extended in this state by a healthcare insurer, health maintenance
31 organization, hospital medical service corporation, or self-insured
32 governmental or church plan in this state.

33 (B) "Health benefit plan" includes:

34 (i) Indemnity and managed care plans; and

35 (ii) Plans providing health benefits to state and
36 public school employees under § 21-5-401 et seq.

1 (C) "Health benefit plan" does not include:

2 (i) A disability income plan;

3 (ii) A credit insurance plan;

4 (iii) Insurance coverage issued as a supplement to
5 liability insurance;

6 (iv) Medical payments under an automobile or
7 homeowners' insurance plan;

8 (v) A health benefit plan provided under Arkansas
9 Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et
10 seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

11 (vi) A plan that provides only indemnity for
12 hospital confinement;

13 (vii) An accident-only plan;

14 (viii) A specified disease plan;

15 (ix) A plan that provides only dental benefits or
16 eye and vision care benefits; or

17 (x) A program or plan authorized and funded under 42
18 U.S.C. 1396a et seq. as approved by the United States Secretary of Health and
19 Human Services;

20 (5)(A) "Healthcare insurer" means an insurance company, hospital
21 and medical service corporation, or health maintenance organization that
22 issues or delivers health benefit plans in this state and is subject to any
23 of the following laws:

24 (i) The insurance laws of this state;

25 (ii) Section 23-75-101 et seq., pertaining to hospital and
26 medical service corporations; or

27 (iii) Section 23-76-101 et seq., pertaining to health
28 maintenance organizations.

29 (B) "Healthcare insurer" does not include an entity that
30 provides only dental benefits or eye and vision care benefits;

31 (6) "Interchangeable biological product" means a biological
32 product that is interchangeable, as "interchangeable" is defined by 42 U.S.C.
33 § 262(i)(3), as it existed on January 1, 2021;

34 (7) "Medically necessary" means healthcare services and supplies
35 that, under the applicable standard of care, are appropriate:

36 (A) To improve or preserve health, life, or function;

1 (B) To slow the deterioration of health, life, or
2 function; or

3 (C) For the early screening, prevention, evaluation,
4 diagnosis, or treatment of a disease, condition, illness, or injury;

5 (8) "Step therapy protocol" means a protocol, policy, or program
6 that establishes the specific sequence in which prescription drugs for a
7 specified medical condition and that are medically appropriate for a patient
8 are covered by a healthcare insurer or health benefit plan;

9 (9) "Step therapy protocol exception" means that a step therapy
10 protocol is overridden in favor of immediate coverage of the healthcare
11 provider's selected prescription drug; and

12 (10)(A) "Utilization review organization" means an individual or
13 entity that performs step therapy for at least one (1) of the following:

14 (i) A healthcare insurer;

15 (ii) A preferred provider organization or health
16 maintenance organization; or

17 (iii) Any other individual or entity that provides,
18 offers to provide, or administers hospital, outpatient, medical, or other
19 health benefits to a person treated by a healthcare provider in this state
20 under a policy, health benefit plan, or contract.

21 (B) A healthcare insurer is a utilization review entity if
22 the healthcare insurer performs step therapy.

23 (C) "Utilization review organization" does not include an
24 insurer of automobile, homeowners, or casualty and commercial liability
25 insurance or the insurer's employees, agents, or contractors.

26
27 23-79-2103. Clinical review criteria.

28 (a)(1) Clinical review criteria used to establish a step therapy
29 protocol shall be based on clinical practice guidelines that:

30 (A) Are developed and endorsed by a multidisciplinary
31 panel of experts that manages conflicts of interest among the members of the
32 writing and review groups by:

33 (i)(a) Requiring members to disclose any potential
34 conflicts of interest with entities, including healthcare insurers, health
35 benefit plans, and pharmaceutical manufacturers.

36 (b) A member shall recuse himself or herself

1 from voting if the member has a conflict of interest;

2 (ii) Using a methodologist to work with writing
3 groups to provide objectivity in data analysis and ranking of evidence
4 through the preparation of evidence tables and facilitating consensus; and

5 (iii) Offering opportunities for public review and
6 comments;

7 (B) Are based on high-quality studies, research, and
8 medical practice;

9 (C) Are created by an explicit and transparent process
10 that:

11 (i) Minimizes biases and conflicts of interest;

12 (ii) Explains the relationship between treatment
13 options and outcomes;

14 (iii) Rates the quality of the evidence supporting
15 recommendations; and

16 (iv) Considers relevant patient subgroups and
17 preferences; and

18 (D) Are continually updated through a review of new
19 evidence, research, and newly developed treatments.

20 (2) Peer-reviewed published medical literature may be
21 substituted for clinical practice guidelines to establish clinical review
22 criteria if the peer-reviewed published medical literature meets the
23 requirements of subdivisions (a)(1)(B) and (C) of this section, when those
24 requirements apply to the available peer-reviewed published medical
25 literature.

26 (3) If establishing a step therapy protocol, a utilization
27 review agent shall take into account the needs of atypical patient
28 populations and diagnoses when establishing clinical review criteria.

29 (4) A healthcare insurer, pharmacy benefit manager, or
30 utilization review organization shall:

31 (A) Upon written request, provide all specific written
32 clinical review criteria relating to the particular condition or disease,
33 including clinical review criteria relating to a step therapy protocol
34 override determination; and

35 (B) Make available such clinical review criteria and other
36 clinical information on its website and to a healthcare professional on

1 behalf of an insured upon written request.

2 (b) This section does not require healthcare insurers, health benefit
3 plans, or the state to set up a new entity to develop clinical review
4 criteria used for step therapy protocols.

5
6 23-79-2104. Exceptions – Transparency.

7 (a)(1) If coverage of a prescription drug for the treatment of any
8 medical condition is restricted for use by a healthcare insurer, health
9 benefit plan, or utilization review organization through the use of a step
10 therapy protocol, a patient and prescribing healthcare provider shall have
11 access to a clear, readily accessible, and convenient process to request a
12 step therapy protocol exception.

13 (2)(A) A healthcare insurer, health benefit plan, or utilization
14 review organization may use its existing medical exceptions process to
15 satisfy the requirement under subdivision (a)(1) of this section.

16 (B) The existing medical exceptions process shall be made
17 easily accessible on the website of the healthcare insurer, health benefit
18 plan, or utilization review organization.

19 (C) Upon request, a healthcare insurer, health benefit
20 plan, or utilization review organization shall disclose to a prescribing
21 healthcare provider all rules and clinical review criteria related to the
22 step therapy protocol, including without limitation the specific information
23 and documentation that is required to be submitted by a prescribing
24 healthcare provider or patient to the healthcare insurer, health benefit
25 plan, or utilization review organization to be considered a complete step
26 therapy protocol exception request.

27 (b) A step therapy protocol exception shall be expeditiously granted
28 if:

29 (1) A required prescription drug is contraindicated or will
30 likely cause an adverse reaction or physical or mental harm to the patient;

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

34 (3) A patient has tried the required prescription drug while
35 under the patient's current or previous health benefit plan, or another
36 prescription drug in the same pharmacologic class or with the same mechanism

1 of action and the prescription drug was discontinued due to lack of efficacy
2 or effectiveness, diminished effect, or an adverse event;

3 (4) A required prescription drug is not in the best interest of
4 the patient, based on medical necessity; or

5 (5) A patient is stable on a prescription drug selected by the
6 patient's healthcare provider for the medical condition under consideration
7 while on a current or previous health benefit plan.

8 (c)(1) The healthcare insurer, health benefit plan, or utilization
9 review organization shall grant or deny a request for a step therapy protocol
10 exception within seventy-two (72) hours of receiving the request.

11 (2) In cases in which exigent circumstances exist, the
12 healthcare insurer, health benefit plan, or utilization review organization
13 shall grant or deny the request within twenty-four (24) hours of receiving
14 the request.

15 (d)(1) A patient covered by a healthcare insurer under a health
16 benefit plan may appeal the denial of a request for a step therapy protocol
17 exception.

18 (2) The health benefit plan shall grant or deny the appeal
19 within seventy-two (72) hours of receiving the appeal.

20 (3) In cases in which exigent circumstances exist, the health
21 benefit plan shall grant or deny the appeal within twenty-four (24) hours of
22 receiving the appeal.

23 (e) If a response by a healthcare insurer, health benefit plan, or
24 utilization review organization is not received within the time allotted
25 under this section, the request for a step therapy protocol exception or the
26 appeal of a denial of such a request shall be deemed granted.

27 (f)(1) If a request for a step therapy protocol exception is
28 incomplete or additional clinically relevant information is required, a
29 healthcare insurer, health benefit plan, or utilization review organization
30 shall notify the prescribing healthcare provider within seventy-two (72)
31 hours of submission, or twenty-four (24) hours in exigent circumstances, of
32 the additional or clinically relevant information that is required in order
33 to approve or deny the step therapy protocol exception request or appeal as
34 described under subdivision (a)(1) of this section.

35 (2) Once the requested information is submitted, the applicable
36 time period to grant or deny a step therapy protocol exception request or

1 appeal shall apply.

2 (3) If a determination or notice of incomplete or clinically
3 relevant information by a healthcare insurer, health benefit plan, or
4 utilization review organization is not received by the prescribing healthcare
5 provider within the time allotted, the step therapy protocol exception or
6 appeal shall be deemed granted.

7 (4) In the event of a denial, a healthcare insurer, health
8 benefit plan, or utilization review organization shall inform the patient of
9 a potential appeal process.

10 (g) Upon the granting of a step therapy protocol exception, a
11 healthcare insurer, health benefit plan, or utilization review organization
12 shall authorize coverage for the prescription drug prescribed by the
13 patient's treating healthcare provider.

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

15 (1) A healthcare insurer, a health benefit plan, or a
16 utilization review organization from requiring:

17 (A) A patient to try a generic equivalent or
18 interchangeable biological product unless such a requirement meets § 23-79-
19 2104(b) pursuant to a step therapy protocol exception request submitted under
20 § 23-79-2104(b); or

21 (B) A pharmacist to effect substitutions of prescription
22 drugs consistent with § 17-92-503; or

23 (2) A healthcare provider from prescribing a prescription drug
24 that is determined to be medically necessary.

25
26 23-79-2105. Applicability.

27 This subchapter applies to a group health benefit plan or offered in
28 connection with a group health plan that provides coverage of a prescription
29 drug under a policy that meets the definition of a medication step therapy
30 protocol whether or not the policy is described as a step therapy protocol.

31

32 SECTION 3. Arkansas Code § 23-99-1103(15)(A), concerning the
33 definition of "prior authorization" under the Prior Authorization
34 Transparency Act, is amended to read as follows:

35 (15)(A) "Prior authorization" means the process by which a
36 utilization review entity determines the medical necessity of an otherwise

1 covered healthcare service before the healthcare service is rendered,
2 including without limitation preadmission review, pretreatment review,
3 utilization review, case management, and fail first protocol, ~~and step~~
4 ~~therapy.~~

5
6 SECTION 4. Arkansas Code § 23-99-1103(17), concerning the definition
7 of "step therapy" under the Prior Authorization Transparency Act, is
8 repealed.

9 ~~(17) "Step therapy" means a protocol requiring that a subscriber~~
10 ~~shall not be allowed coverage of a prescription drug ordered by the~~
11 ~~subscriber's healthcare provider until other less expensive drugs have been~~
12 ~~tried;~~

13
14 SECTION 5. Arkansas Code § 23-99-1114 is amended to read as follows:
15 23-99-1114. Limitations on step therapy - Definition.

16 ~~(a) If a utilization review entity has required a healthcare provider~~
17 ~~to utilize step therapy for a specific prescription drug for a subscriber,~~
18 ~~the utilization review entity shall not require the healthcare provider to~~
19 ~~utilize step therapy a second time for that same prescription drug, even~~
20 ~~though the utilization review entity or healthcare insurer may change its~~
21 ~~prescribed drug formulary or change to a new or different pharmacy benefits~~
22 ~~manager or utilization review entity.~~

23 ~~(b) In order to ensure compliance with this section, if a healthcare~~
24 ~~insurer or utilization review entity changes its pharmacy benefits manager,~~
25 ~~the healthcare insurer or utilization review entity shall provide the new~~
26 ~~pharmacy benefits manager with adequate historical claims data to identify~~
27 ~~all subscribers who have been required to utilize step therapy and the~~
28 ~~results of that step therapy.~~

29 ~~(c) Except as provided in subsection (d) of this section,~~
30 ~~notwithstanding subsection (a) of this section, a utilization review entity~~
31 ~~may require the utilization of step therapy if:~~

32 ~~(1) A new drug has been introduced to treat the patient's~~
33 ~~condition or an existing therapy is considered clinically appropriate for~~
34 ~~treatment of the patient's condition; or~~

35 ~~(2) The patient's medical or physical condition has changed~~
36 ~~substantially since the step therapy was required that makes the use of~~

1 ~~repeat step therapy appropriate.~~

2 ~~(d)(1)(a)~~ An insurance policy that provides coverage for the treatment
3 of metastatic cancer shall not limit or exclude coverage under the health
4 benefit plan for a drug approved by the United States Food and Drug
5 Administration that is on the prescription drug formulary of the insurance
6 policy by mandating that a covered person with metastatic cancer undergo step
7 therapy unless the preferred drug is consistent with best practices that:

8 ~~(A)(1)~~ Are used for the treatment of metastatic cancer or
9 associated conditions under:

10 ~~(i)(A)~~ The United States Food and Drug Administration-
11 approved indication; or

12 ~~(ii)(B)~~ The National Comprehensive Cancer Network Drugs
13 and Biologics Compendium indication; or

14 ~~(B)(2)~~ Use evidence-based, peer-reviewed, recognized medical
15 literature.

16 ~~(2)(b)~~ As used in ~~subdivision (d)(1)~~ subsection (a) of this section,
17 “metastatic cancer” means cancer that has spread from a primary or original
18 site of the cancer to surrounding or nearby tissues, lymph nodes, or other
19 parts of the body.

20

21 SECTION 6. Arkansas Code § 23-99-1115(c)(1), concerning the process
22 for appealing adverse determination and restriction or denial of healthcare
23 service, is amended to read as follows:

24 (c)(1) When a healthcare service for the treatment or diagnosis of any
25 medical condition is restricted or denied in favor of ~~step therapy~~ or a fail
26 first protocol preferred by the utilization review entity, the subscriber’s
27 healthcare provider shall have access to a clear and convenient process to
28 expeditiously request an override of that restriction or denial from the
29 utilization review entity or healthcare insurer.

30

31 SECTION 7. TEMPORARY LANGUAGE. DO NOT CODIFY. Rules.

32 (a) The Insurance Commissioner shall promulgate rules necessary to
33 implement Section 2 of this act.

34 (b)(1) When adopting the initial rules to implement Section 2 of this
35 act, the final rule shall be filed with the Secretary of State for adoption
36 under § 25-15-204(f):

1 (A) On or before January 1, 2022; or
2 (B) If approval under § 10-3-309 has not occurred by
3 January 1, 2022, as soon as practicable after approval under § 10-3-309.

4 (2) The commissioner shall file the proposed rule with the
5 Legislative Council under § 10-3-309(c) sufficiently in advance of January 1,
6 2022, so that the Legislative Council may consider the rule for approval
7 before January 1, 2022.

8
9 SECTION 8. DO NOT CODIFY. Effective date.
10 Section 2 of this act is effective on and after January 1, 2022.

11
12
13 /s/Bledsoe
14

15
16 APPROVED: 2/10/21
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36

1 State of Arkansas
2 93rd General Assembly
3 Regular Session, 2021
4

A Bill

SENATE BILL 446

5 By: Senator Bledsoe
6 By: Representative Vaught
7

For An Act To Be Entitled

9 AN ACT TO CLARIFY THE APPLICABILITY OF STEP THERAPY
10 PROTOCOLS; TO AMEND THE DEFINITION OF "HEALTH BENEFIT
11 PLAN" TO INCLUDE INDIVIDUAL QUALIFIED HEALTH
12 INSURANCE PLANS; AND FOR OTHER PURPOSES.
13
14

Subtitle

15 TO CLARIFY THE APPLICABILITY OF STEP
16 THERAPY PROTOCOLS; AND TO AMEND THE
17 DEFINITION OF "HEALTH BENEFIT PLAN" TO
18 INCLUDE INDIVIDUAL QUALIFIED HEALTH
19 INSURANCE PLANS.
20
21
22

23 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:
24

25 SECTION 1. Arkansas Code § 23-79-2102(4), as enacted by Acts 2021, No.
26 97, and concerning the definition of "health benefit plan" used in the
27 regulation of step therapy protocols, is amended to read as follows:

28 (4)(A) "Health benefit plan" means an individual, blanket, or
29 any group plan, policy, or contract for healthcare services issued, renewed,
30 or extended in this state by a healthcare insurer, health maintenance
31 organization, hospital medical service corporation, or self-insured
32 governmental or church plan in this state.

33 (B) "Health benefit plan" includes:

34 (i) Indemnity and managed care plans; ~~and~~
35 (ii) Plans providing health benefits to state and
36 public school employees under § 21-5-401 et seq.; and



1 (iii) Individual qualified health insurance plans
2 under § 23-61-1001 et seq.

3 (C) "Health benefit plan" does not include:

4 (i) A disability income plan;

5 (ii) A credit insurance plan;

6 (iii) Insurance coverage issued as a supplement to
7 liability insurance;

8 (iv) Medical payments under an automobile or
9 homeowners' insurance plan;

10 (v) A health benefit plan provided under Arkansas
11 Constitution, Article 5, § 32, the Workers' Compensation Law, § 11-9-101 et
12 seq., and the Public Employee Workers' Compensation Act, § 21-5-601 et seq.;

13 (vi) A plan that provides only indemnity for
14 hospital confinement;

15 (vii) An accident-only plan;

16 (viii) A specified disease plan;

17 (ix) A plan that provides only dental benefits or
18 eye and vision care benefits; or

19 (x) A program or plan authorized ~~and funded~~ under 42
20 U.S.C. § 1396a et seq., as it existed on January 1, 2021, as approved by the
21 United States Secretary of Health and Human Services, excluding individual
22 qualified health insurance plans under § 23-61-1001 et seq.

23
24
25 **APPROVED: 4/12/21**
26
27
28
29
30
31
32
33
34
35
36