

3419--C

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I N S E N A T E

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Introduced by Sens. YOUNG, AKSHAR, AVELLA, BRESLIN, CARLUCCI, GOLDEN, KAMINSKY, LANZA, LARKIN, LATIMER, LAVALLE, MARCHIONE, PARKER, PERKINS, RIVERA, SAVINO, SQUADRON, VALESKY -- read twice and ordered printed, and when printed to be committed to the Committee on Insurance -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- recommitted to the Committee on Insurance in accordance with Senate Rule 6, sec. 8 -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- 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 expedited utilization review of prescription drugs

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

1 Section 1. Paragraph 10 of subsection (b) of section 3217-a of the  
2 insurance law, as added by chapter 705 of the laws of 1996, is amended  
3 to read as follows:  
4 (10) upon written request, provide specific written clinical review  
5 criteria relating to a particular condition or disease INCLUDING CLIN-  
6 ICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETER-  
7 MINATION PURSUANT TO SUBSECTION (C-1), SUBSECTION (C-2) AND SUBSECTION  
8 (C-3) OF SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where  
9 appropriate, other clinical information which the insurer might consider  
10 in its utilization review and the insurer may include with the informa-  
11 tion a description of how it will be used in the utilization review  
12 process; provided, however, that to the extent such information is  
13 proprietary to the insurer, the insured or prospective insured shall  
14 only use the information for the purposes of assisting the enrollee or  
15 prospective enrollee in evaluating the covered services provided by the  
16 organization. SUCH CLINICAL REVIEW CRITERIA, AND OTHER CLINICAL INFORMA-  
17 TION SHALL ALSO BE MADE AVAILABLE TO A HEALTH CARE PROFESSIONAL AS

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

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1 DEFINED IN SUBSECTION (F) OF SECTION FORTY-NINE HUNDRED OF THIS CHAPTER,  
2 ON BEHALF OF AN INSURED AND UPON WRITTEN REQUEST;

3 S 2. Paragraph 10 of subsection (b) of section 4324 of the insurance  
4 law, as added by chapter 705 of the laws of 1996, is amended to read as  
5 follows:

6 (10) upon written request, provide specific written clinical review  
7 criteria relating to a particular condition or disease INCLUDING CLIN-  
8 ICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETER-  
9 MINATION PURSUANT TO SUBSECTION (C-1), SUBSECTION (C-2) AND SUBSECTION  
10 (C-3) OF SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where  
11 appropriate, other clinical information which the corporation might  
12 consider in its utilization review and the corporation may include with  
13 the information a description of how it will be used in the utilization  
14 review process; provided, however, that to the extent such information  
15 is proprietary to the corporation, the subscriber or prospective  
16 subscriber shall only use the information for the purposes of assisting  
17 the subscriber or prospective subscriber in evaluating the covered  
18 services provided by the organization. SUCH CLINICAL REVIEW CRITERIA,  
19 AND OTHER CLINICAL INFORMATION SHALL ALSO BE MADE AVAILABLE TO A HEALTH  
20 CARE PROFESSIONAL AS DEFINED IN SUBSECTION (F) OF SECTION FORTY-NINE  
21 HUNDRED OF THIS CHAPTER, ON BEHALF OF AN INSURED AND UPON WRITTEN  
22 REQUEST;

23 S 3. Section 4900 of the insurance law is amended by adding two new  
24 subsections (g-8) and (g-9) to read as follows:

25 (G-8) "STEP THERAPY PROTOCOL OVERRIDE DETERMINATION" MEANS A DETERMI-  
26 NATION MADE BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBSECTION (I)  
27 OF THIS SECTION TO OVERRIDE A STEP THERAPY PROTOCOL PURSUANT TO  
28 SUBSECTIONS (C-1), (C-2) AND (C-3) OF SECTION FORTY-NINE HUNDRED THREE  
29 OF THIS TITLE GRANTING COVERAGE FOR THE HEALTH CARE PROFESSIONAL'S  
30 SELECTED PRESCRIPTION DRUG OR DRUGS. ANY STEP THERAPY OVERRIDE DETERMI-  
31 NATION AS DEFINED BY THIS SUBSECTION SHALL BE ELIGIBLE FOR APPEAL BY AN  
32 INSURED PURSUANT TO THIS ARTICLE.

33 (G-9) "STEP THERAPY PROTOCOL" MEANS A POLICY, PROTOCOL OR PROGRAM  
34 ESTABLISHED BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBSECTION (I)  
35 OF THIS SECTION THAT ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH  
36 PRESCRIPTION DRUGS FOR A SPECIFIED MEDICAL CONDITION ARE APPROVED FOR A  
37 PARTICULAR INSURED. NOTHING IN THIS CHAPTER SHALL IMPAIR OR PREVENT AN  
38 INSURED FROM HAVING THE RIGHT TO APPEAL PURSUANT TO THIS ARTICLE RELAT-  
39 ING TO THE IMPOSITION OF A STEP THERAPY PROTOCOL.

40 S 4. Subsection (a) of section 4902 of the insurance law is amended by  
41 adding two new paragraphs 10 and 11 to read as follows:

42 10. WHEN ESTABLISHING A STEP THERAPY PROTOCOL, A UTILIZATION REVIEW  
43 AGENT SHALL UTILIZE RECOGNIZED EVIDENCE-BASED AND PEER REVIEWED CLINICAL  
44 REVIEW CRITERIA THAT ALSO TAKES INTO ACCOUNT THE NEEDS OF ATYPICAL  
45 PATIENT POPULATIONS AND DIAGNOSES WHEN ESTABLISHING THE CLINICAL REVIEW  
46 CRITERIA.

47 11. WHEN CONDUCTING UTILIZATION REVIEW FOR A STEP THERAPY PROTOCOL  
48 OVERRIDE DETERMINATION, A UTILIZATION REVIEW AGENT SHALL UTILIZE, IN  
49 ADDITION TO ANY OTHER REQUIREMENTS OF THIS ARTICLE, RECOGNIZED  
50 EVIDENCE-BASED AND PEER REVIEWED CLINICAL REVIEW CRITERIA THAT IS APPRO-  
51 PRIATE FOR THE INSURED AND THE INSURED'S MEDICAL CONDITION.

52 S 5. Section 4903 of the insurance law is amended by adding three new  
53 subsections (c-1), (c-2) and (c-3) to read as follows:

54 (C-1) A UTILIZATION REVIEW AGENT SHALL GRANT A STEP THERAPY PROTOCOL  
55 OVERRIDE DETERMINATION WITHIN SEVENTY-TWO HOURS OF THE RECEIPT OF INFOR-

1 MATION THAT INCLUDES SUPPORTING RATIONALE AND DOCUMENTATION FROM A  
2 HEALTH CARE PROFESSIONAL WHICH DEMONSTRATES THAT:

3 (1) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS CONTRAINDICATED OR WILL  
4 LIKELY CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE  
5 INSURED;

6 (2) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS EXPECTED TO BE INEFFEC-  
7 TIVE BASED ON THE KNOWN CLINICAL HISTORY AND CONDITIONS OF THE INSURED  
8 AND THE INSURED'S PRESCRIPTION DRUG REGIMEN;

9 (3) THE INSURED HAS TRIED THE REQUIRED PRESCRIPTION DRUG OR DRUGS  
10 WHILE UNDER THEIR CURRENT OR A PREVIOUS HEALTH INSURANCE OR HEALTH BENE-  
11 FIT PLAN, OR ANOTHER PRESCRIPTION DRUG OR DRUGS IN THE SAME PHARMACOLOG-  
12 IC CLASS OR WITH THE SAME MECHANISM OF ACTION AND SUCH PRESCRIPTION DRUG  
13 OR DRUGS WAS DISCONTINUED DUE TO LACK OF EFFICACY OR EFFECTIVENESS,  
14 DIMINISHED EFFECT, OR AN ADVERSE EVENT;

15 (4) THE INSURED IS STABLE ON A PRESCRIPTION DRUG OR DRUGS SELECTED BY  
16 THEIR HEALTH CARE PROFESSIONAL FOR THE MEDICAL CONDITION UNDER CONSIDER-  
17 ATION, PROVIDED THAT THIS SHALL NOT PREVENT A UTILIZATION REVIEW AGENT  
18 FROM REQUIRING AN INSURED TO TRY AN AB-RATED GENERIC EQUIVALENT PRIOR TO  
19 PROVIDING COVERAGE FOR THE EQUIVALENT BRAND NAME PRESCRIPTION DRUG OR  
20 DRUGS; OR

21 (5) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS NOT IN THE BEST INTER-  
22 EST OF THE INSURED BECAUSE IT WILL LIKELY CAUSE A SIGNIFICANT BARRIER TO  
23 THE INSURED'S ADHERENCE TO OR COMPLIANCE WITH THE INSURED'S PLAN OF  
24 CARE, WILL LIKELY WORSEN A COMORBID CONDITION OF THE INSURED, OR WILL  
25 LIKELY DECREASE THE COVERED INDIVIDUAL'S ABILITY TO ACHIEVE OR MAINTAIN  
26 REASONABLE FUNCTIONAL ABILITY IN PERFORMING DAILY ACTIVITIES.

27 (C-2) FOR AN INSURED WITH A MEDICAL CONDITION THAT PLACES THE HEALTH  
28 OF THE INSURED IN SERIOUS JEOPARDY WITHOUT THE PRESCRIPTION DRUG OR  
29 DRUGS PRESCRIBED BY THE INSURED'S HEALTH CARE PROFESSIONAL, THE STEP  
30 THERAPY PROTOCOL OVERRIDE DETERMINATION SHALL BE GRANTED WITHIN TWENTY-  
31 FOUR HOURS OF THE RECEIPT OF INFORMATION THAT INCLUDES SUPPORTING  
32 RATIONALE AND DOCUMENTATION FROM A HEALTH CARE PROFESSIONAL DEMONSTRAT-  
33 ING ONE OR MORE OF THE STANDARDS PROVIDED FOR IN SUBSECTION (C-1) OF  
34 THIS SECTION.

35 (C-3) UPON A DETERMINATION THAT THE STEP THERAPY PROTOCOL SHOULD BE  
36 OVERRIDDEN, THE HEALTH PLAN SHALL AUTHORIZE IMMEDIATE COVERAGE FOR THE  
37 PRESCRIPTION DRUG PRESCRIBED BY THE INSURED'S TREATING HEALTH CARE  
38 PROFESSIONAL.

39 S 6. Subsection (g) of section 4903 of the insurance law, as added by  
40 chapter 586 of the laws of 1998, is amended to read as follows:

41 (g) Failure by the utilization review agent to make a determination  
42 within the time periods prescribed in this section shall be deemed to be  
43 an adverse determination subject to appeal pursuant to section four  
44 thousand nine hundred four of this title, PROVIDED, HOWEVER, THAT FAIL-  
45 URE TO MEET SUCH TIME PERIODS FOR A STEP THERAPY PROTOCOL AS DEFINED IN  
46 SUBSECTION (G-9) OF SECTION FORTY-NINE HUNDRED OF THIS TITLE OR A STEP  
47 THERAPY PROTOCOL OVERRIDE DETERMINATION PURSUANT TO SUBSECTIONS (C-1),  
48 (C-2) AND (C-3) OF THIS SECTION SHALL BE DEEMED TO BE AN OVERRIDE OF THE  
49 STEP THERAPY PROTOCOL.

50 S 7. Paragraph (j) of subdivision 2 of section 4408 of the public  
51 health law, as added by chapter 705 of the laws of 1996, is amended to  
52 read as follows:

53 (j) upon written request, provide specific written clinical review  
54 criteria relating to a particular condition or disease INCLUDING CLIN-  
55 ICAL REVIEW CRITERIA RELATING TO A STEP THERAPY PROTOCOL OVERRIDE DETER-  
56 MINATION PURSUANT TO SUBDIVISIONS THREE-A, THREE-B AND THREE-C OF

1 SECTION FORTY-NINE HUNDRED THREE OF THIS CHAPTER, and, where appropri-  
2 ate, other clinical information which the organization might consider in  
3 its utilization review and the organization may include with the infor-  
4 mation a description of how it will be used in the utilization review  
5 process; provided, however, that to the extent such information is  
6 proprietary to the organization, the enrollee or prospective enrollee  
7 shall only use the information for the purposes of assisting the enrol-  
8 lee or prospective enrollee in evaluating the covered services provided  
9 by the organization. SUCH CLINICAL REVIEW CRITERIA, AND OTHER CLINICAL  
10 INFORMATION SHALL ALSO BE MADE AVAILABLE TO A HEALTH CARE PROFESSIONAL  
11 AS DEFINED IN SUBDIVISION SIX OF SECTION FORTY-NINE HUNDRED OF THIS  
12 CHAPTER, ON BEHALF OF AN ENROLLEE AND UPON WRITTEN REQUEST;

13 S 8. Section 4900 of the public health law is amended by adding two  
14 new subdivisions 7-f-2 and 7-f-3 to read as follows:

15 7-F-2. "STEP THERAPY PROTOCOL OVERRIDE DETERMINATION" MEANS A DETERMI-  
16 NATION MADE BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBDIVISION NINE  
17 OF THIS SECTION TO OVERRIDE A STEP THERAPY PROTOCOL PURSUANT TO SUBDIVI-  
18 SIONS THREE-A, THREE-B AND THREE-C OF SECTION FORTY-NINE HUNDRED THREE  
19 OF THIS TITLE GRANTING COVERAGE FOR THE HEALTH CARE PROFESSIONAL'S  
20 SELECTED PRESCRIPTION DRUG OR DRUGS. ANY STEP THERAPY PROTOCOL OVERRIDE  
21 DETERMINATION AS DEFINED BY THIS SUBDIVISION SHALL BE ELIGIBLE FOR  
22 APPEAL BY AN ENROLLEE PURSUANT TO THIS ARTICLE.

23 7-F-3. "STEP THERAPY PROTOCOL" MEANS A POLICY, PROTOCOL OR PROGRAM  
24 ESTABLISHED BY A UTILIZATION REVIEW AGENT AS DEFINED IN SUBDIVISION NINE  
25 OF THIS SECTION THAT ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH  
26 PRESCRIPTION DRUGS FOR A SPECIFIED MEDICAL CONDITION ARE APPROVED FOR A  
27 PARTICULAR ENROLLEE. NOTHING IN THIS CHAPTER SHALL IMPAIR OR PREVENT AN  
28 INSURED FROM HAVING THE RIGHT TO APPEAL PURSUANT TO THIS ARTICLE RELAT-  
29 ING TO THE IMPOSITION OF A STEP THERAPY PROTOCOL.

30 S 9. Section 4902 of the public health law is amended by adding two  
31 new subdivisions 3 and 4 to read as follows:

32 3. WHEN ESTABLISHING A STEP THERAPY PROTOCOL, A UTILIZATION REVIEW  
33 AGENT SHALL UTILIZE RECOGNIZED EVIDENCE-BASED AND PEER REVIEWED CLINICAL  
34 REVIEW CRITERIA THAT TAKES INTO ACCOUNT THE NEEDS OF ATYPICAL PATIENT  
35 POPULATIONS AND DIAGNOSES AS WELL WHEN ESTABLISHING THE CLINICAL REVIEW  
36 CRITERIA.

37 4. WHEN CONDUCTING UTILIZATION REVIEW FOR A STEP THERAPY PROTOCOL  
38 OVERRIDE DETERMINATION, A UTILIZATION REVIEW AGENT SHALL UTILIZE, IN  
39 ADDITION TO ANY OTHER REQUIREMENTS OF THIS ARTICLE, RECOGNIZED  
40 EVIDENCE-BASED AND PEER REVIEWED CLINICAL REVIEW CRITERIA THAT IS APPRO-  
41 PRIATE FOR THE ENROLLEE AND THE ENROLLEE'S MEDICAL CONDITION.

42 S 10. Section 4903 of the public health law is amended by adding three  
43 new subdivisions 3-a, 3-b and 3-c to read as follows:

44 3-A. A UTILIZATION REVIEW AGENT SHALL GRANT A STEP THERAPY PROTOCOL  
45 OVERRIDE DETERMINATION WITHIN SEVENTY-TWO HOURS OF THE RECEIPT OF INFOR-  
46 MATION THAT INCLUDES SUPPORTING RATIONALE AND DOCUMENTATION FROM A  
47 HEALTH CARE PROFESSIONAL WHICH DEMONSTRATES THAT:

48 (A) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS CONTRAINDICATED, WILL  
49 LIKELY CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE  
50 ENROLLEE;

51 (B) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS EXPECTED TO BE INEFFEC-  
52 TIVE BASED ON THE KNOWN CLINICAL HISTORY AND CONDITIONS OF THE ENROLLEE  
53 AND THE ENROLLEE'S PRESCRIPTION DRUG REGIMEN;

54 (C) THE ENROLLEE HAS TRIED THE REQUIRED PRESCRIPTION DRUG OR DRUGS  
55 WHILE UNDER THEIR CURRENT OR A PREVIOUS HEALTH INSURANCE OR HEALTH BENE-  
56 FIT PLAN, OR ANOTHER PRESCRIPTION DRUG OR DRUGS IN THE SAME PHARMACOLOG-

1 IC CLASS OR WITH THE SAME MECHANISM OF ACTION AND SUCH PRESCRIPTION DRUG  
2 OR DRUGS WAS DISCONTINUED DUE TO LACK OF EFFICACY OR EFFECTIVENESS,  
3 DIMINISHED EFFECT, OR AN ADVERSE EVENT;

4 (D) THE ENROLLEE IS STABLE ON A PRESCRIPTION DRUG OR DRUGS SELECTED BY  
5 THEIR HEALTH CARE PROFESSIONAL FOR THE MEDICAL CONDITION UNDER CONSIDER-  
6 ATION, PROVIDED THAT THIS SHALL NOT PREVENT A UTILIZATION REVIEW AGENT  
7 FROM REQUIRING AN INSURED TO TRY AN AB-RATED GENERIC EQUIVALENT PRIOR TO  
8 PROVIDING COVERAGE FOR THE EQUIVALENT BRAND NAME PRESCRIPTION DRUG OR  
9 DRUGS; OR

10 (E) THE REQUIRED PRESCRIPTION DRUG OR DRUGS IS NOT IN THE BEST INTER-  
11 EST OF THE ENROLLEE BECAUSE IT WILL LIKELY CAUSE A SIGNIFICANT BARRIER  
12 TO THE ENROLLEE'S ADHERENCE TO OR COMPLIANCE WITH THE ENROLLEE'S PLAN OF  
13 CARE, WILL LIKELY WORSEN A COMORBID CONDITION OF THE ENROLLEE, OR WILL  
14 LIKELY DECREASE THE COVERED ENROLLEE'S ABILITY TO ACHIEVE OR MAINTAIN  
15 REASONABLE FUNCTIONAL ABILITY IN PERFORMING DAILY ACTIVITIES.

16 3-B. FOR AN ENROLLEE WITH A MEDICAL CONDITION THAT PLACES THE HEALTH  
17 OF THE INSURED IN SERIOUS JEOPARDY WITHOUT THE PRESCRIPTION DRUG OR  
18 DRUGS PRESCRIBED BY THE INSURED'S HEALTH CARE PROFESSIONAL, THE STEP  
19 THERAPY PROTOCOL OVERRIDE DETERMINATION SHALL BE GRANTED WITHIN TWENTY-  
20 FOUR HOURS OF THE RECEIPT OF INFORMATION THAT INCLUDES SUPPORTING  
21 RATIONALE AND DOCUMENTATION FROM A HEALTH CARE PROFESSIONAL DEMONSTRAT-  
22 ING ONE OR MORE OF THE STANDARDS PROVIDED FOR IN SUBDIVISION THREE-A OF  
23 THIS SECTION.

24 3-C. UPON A DETERMINATION THAT THE STEP THERAPY PROTOCOL SHOULD BE  
25 OVERRIDDEN, THE HEALTH PLAN SHALL AUTHORIZE IMMEDIATE COVERAGE FOR THE  
26 PRESCRIPTION DRUG OR DRUGS PRESCRIBED BY THE ENROLLEE'S TREATING HEALTH  
27 CARE PROFESSIONAL.

28 S 11. Subdivision 7 of section 4903 of the public health law, as added  
29 by chapter 586 of the laws of 1998, is amended to read as follows:

30 7. Failure by the utilization review agent to make a determination  
31 within the time periods prescribed in this section shall be deemed to be  
32 an adverse determination subject to appeal pursuant to section [forty  
33 nine] FORTY-NINE hundred four of this title, PROVIDED, HOWEVER, THAT  
34 FAILURE TO MEET SUCH TIME PERIODS FOR A STEP THERAPY PROTOCOL AS DEFINED  
35 IN SUBDIVISION SEVEN-F-THREE OF SECTION FORTY-NINE HUNDRED OF THIS TITLE  
36 OR A STEP THERAPY PROTOCOL OVERRIDE DETERMINATION PURSUANT TO SUBDIVI-  
37 SIONS THREE-A, THREE-B AND THREE-C OF THIS SECTION SHALL BE DEEMED TO BE  
38 AN OVERRIDE OF THE STEP THERAPY PROTOCOL.

39 S 12. This act shall not be construed to prevent: a health care plan  
40 or utilization review agent from requiring a patient to try an AB-rated  
41 generic equivalent prior to providing coverage for the equivalent brand-  
42 ed prescription drug; or a health care provider from prescribing a  
43 prescription drug that is determined to be medically appropriate.

44 S 13. This act shall take effect on January 1, 2017, and shall apply  
45 only to health insurance and health benefit plans delivered, issued for  
46 delivery, or renewed after such date, provided further that effective  
47 immediately the superintendent of financial services is authorized to  
48 promulgate such rules and regulations and take any other measures as may  
49 be necessary for the timely implementation of this act.