

**HOUSE . . . . . No. 3644**

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The Commonwealth of Massachusetts

PRESENTED BY:

*Edward F. Coppinger*

*To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:*

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act relative to certain genetically targeted drug coverage for Duchenne Muscular Dystrophy.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
<i>Edward F. Coppinger</i>	<i>10th Suffolk</i>	<i>3/27/2017</i>

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The Commonwealth of Massachusetts

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**In the One Hundred and Ninetieth General Court  
(2017-2018)**  
\_\_\_\_\_

An Act relative to certain genetically targeted drug coverage for Duchenne Muscular Dystrophy.

*Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:*

1           SECTION 1. Chapter 32A of the General Laws, as amended by chapter 233 of the acts  
2 of 2016, is hereby amended by inserting after section 17O the following section:-

3           Section 17P. Any coverage offered by the commission to an active or retired employee  
4 of the commonwealth insured under the group insurance commission shall provide coverage for  
5 genetically targeted drugs for Duchenne muscular dystrophy when (1) the drug has been  
6 approved by the FDA for the prescribed use, including pursuant to the accelerated approval  
7 provisions of section 506(c) of the Federal Food, Drug, and Cosmetic Act, and as such shall not  
8 be considered experimental, investigational or unproven; and (2) the drug has been ordered or  
9 prescribed and determined to be medically necessary by a licensed physician who has thoroughly  
10 evaluated the patient and either possesses expertise in Duchenne muscular dystrophy or has  
11 consulted with an expert, identified by the prescribing physician, in Duchenne muscular  
12 dystrophy who has determined the drug to be medically necessary for the patient. The benefits  
13 in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-  
14 pocket limits than any other benefit provided by the commission. For purposes of this section

15 the term “genetically targeted drug” shall mean a drug for which the approved use may result in  
16 the modulation, including suppression, up-regulation, or activation, of the function of a gene or  
17 its associated gene product and incorporates or utilizes non-replicating nucleic acid or analogous  
18 compounds to treat one or more patient subgroups, including subgroups of patients with different  
19 mutations of a gene.

20 SECTION 2. Chapter 118E of the General Laws, as amended by chapter 233 of the acts  
21 of 2016, is hereby amended by inserting after section 10J, the following section:-

22 Section 10K. The division shall provide coverage for genetically targeted drugs for  
23 Duchenne muscular dystrophy when (1) the drug has been approved by the FDA for the  
24 prescribed use, including pursuant to the accelerated approval provisions of section 506(c) of the  
25 Federal Food, Drug, and Cosmetic Act, and as such shall not be considered experimental,  
26 investigational or unproven; and (2) the drug has been ordered or prescribed and determined to  
27 be medically necessary by a licensed physician who has thoroughly evaluated the patient and  
28 either possesses expertise in Duchenne muscular dystrophy or has consulted with an expert,  
29 identified by the prescribing physician, in Duchenne muscular dystrophy who has determined the  
30 drug to be medically necessary for the patient. The benefits in this section shall not be subject to  
31 any greater deductible, coinsurance, copayments or out-of-pocket limits than any other benefit  
32 provided by the commission. For purposes of this section the term “genetically targeted drug”  
33 shall mean a drug for which the approved use may result in the modulation, including  
34 suppression, up-regulation, or activation, of the function of a gene or its associated gene product  
35 and incorporates or utilizes non-replicating nucleic acid or analogous compounds to treat one or  
36 more patient subgroups, including subgroups of patients with different mutations of a gene.

37 SECTION 3. Chapter 175 of the General Laws, as amended by chapter 233 of the acts of  
38 2016, is hereby amended by inserting after section 47II the following section:-

39 Section 47JJ. Any individual policy of accident or sickness insurance issued pursuant to  
40 this chapter shall provide coverage for genetically targeted drugs for Duchenne muscular  
41 dystrophy when (1) the drug has been approved by the FDA for the prescribed use, including  
42 pursuant to the accelerated approval provisions of section 506(c) of the Federal Food, Drug, and  
43 Cosmetic Act, and as such shall not be considered experimental, investigational or unproven; and  
44 (2) the drug has been ordered or prescribed and determined to be medically necessary by a  
45 licensed physician who has thoroughly evaluated the patient and either possesses expertise in  
46 Duchenne muscular dystrophy or has consulted with an expert, identified by the prescribing  
47 physician, in Duchenne muscular dystrophy who has determined the drug to be medically  
48 necessary for the patient. The benefits in this section shall not be subject to any greater  
49 deductible, coinsurance, copayments or out-of-pocket limits than any other benefit provided by  
50 the commission. For purposes of this section the term “genetically targeted drug” shall mean a  
51 drug for which the approved use may result in the modulation, including suppression, up-  
52 regulation, or activation, of the function of a gene or its associated gene product and incorporates  
53 or utilizes non-replicating nucleic acid or analogous compounds to treat one or more patient  
54 subgroups, including subgroups of patients with different mutations of a gene.

55 SECTION 4. Chapter 176A of the General Laws, as amended by chapter 233 of the acts  
56 of 2016, is hereby amended by inserting after section 8KK the following section:-

57 Section 8LL. A contract between a subscriber and the corporation under an individual  
58 group or hospital service plan which is delivered, issued or renewed within the commonwealth

59 shall provide coverage for genetically targeted drugs for Duchenne muscular dystrophy when (1)  
60 the drug has been approved by the FDA for the prescribed use, including pursuant to the  
61 accelerated approval provisions of section 506(c) of the Federal Food, Drug, and Cosmetic Act,  
62 and as such shall not be considered experimental, investigational or unproven; and (2) the drug  
63 has been ordered or prescribed and determined to be medically necessary by a licensed physician  
64 who has thoroughly evaluated the patient and either possesses expertise in Duchenne muscular  
65 dystrophy or has consulted with an expert, identified by the prescribing physician, in Duchenne  
66 muscular dystrophy who has determined the drug to be medically necessary for the patient. The  
67 benefits in this section shall not be subject to any greater deductible, coinsurance, copayments or  
68 out-of-pocket limits than any other benefit provided by the commission. For purposes of this  
69 section the term “genetically targeted drug” shall mean a drug for which the approved use may  
70 result in the modulation, including suppression, up-regulation, or activation, of the function of a  
71 gene or its associated gene product and incorporates or utilizes non-replicating nucleic acid or  
72 analogous compounds to treat one or more patient subgroups, including subgroups of patients  
73 with different mutations of a gene.

74 SECTION 5. Chapter 176B of the General Laws, as amended by chapter 233 of the acts  
75 of 2016, is hereby amended by inserting after section 4KK the following section:-

76 Section 4LL. Any subscription certificate under an individual or group medical service  
77 agreement delivered, issued or renewed within the commonwealth shall provide coverage for  
78 genetically targeted drugs for Duchenne muscular dystrophy when (1) the drug has been  
79 approved by the FDA for the prescribed use, including pursuant to the accelerated approval  
80 provisions of section 506(c) of the Federal Food, Drug, and Cosmetic Act, and as such shall not  
81 be considered experimental, investigational or unproven; and (2) the drug has been ordered or

82 prescribed and determined to be medically necessary by a licensed physician who has thoroughly  
83 evaluated the patient and either possesses expertise in Duchenne muscular dystrophy or has  
84 consulted with an expert, identified by the prescribing physician, in Duchenne muscular  
85 dystrophy who has determined the drug to be medically necessary for the patient. The benefits  
86 in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-  
87 pocket limits than any other benefit provided by the commission. For purposes of this section  
88 the term “genetically targeted drug” shall mean a drug for which the approved use may result in  
89 the modulation, including suppression, up-regulation, or activation, of the function of a gene or  
90 its associated gene product and incorporates or utilizes non-replicating nucleic acid or analogous  
91 compounds to treat one or more patient subgroups, including subgroups of patients with different  
92 mutations of a gene.

93 SECTION 6. Chapter 176G of the General Laws, as amended by chapter 233 of the acts  
94 of 2016, is hereby amended by inserting after section 4CC the following section:-

95 Section 4DD. Any individual or group health maintenance contract shall provide  
96 coverage for genetically targeted drugs for Duchenne muscular dystrophy when (1) the drug has  
97 been approved by the FDA for the prescribed use, including pursuant to the accelerated approval  
98 provisions of section 506(c) of the Federal Food, Drug, and Cosmetic Act, and as such shall not  
99 be considered experimental, investigational or unproven; and (2) the drug has been ordered or  
100 prescribed and determined to be medically necessary by a licensed physician who has thoroughly  
101 evaluated the patient and either possesses expertise in Duchenne muscular dystrophy or has  
102 consulted with an expert, identified by the prescribing physician, in Duchenne muscular  
103 dystrophy who has determined the drug to be medically necessary for the patient. The benefits  
104 in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-

105 pocket limits than any other benefit provided by the commission. For purposes of this section  
106 the term “genetically targeted drug” shall mean a drug for which the approved use may result in  
107 the modulation, including suppression, up-regulation, or activation, of the function of a gene or  
108 its associated gene product and incorporates or utilizes non-replicating nucleic acid or analogous  
109 compounds to treat one or more patient subgroups, including subgroups of patients with different  
110 mutations of a gene.