

HOUSE No. 3644

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>

HOUSE No. 3644

The Commonwealth of Massachusetts

**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.