

HOUSE No. 4865

Substituted by the House, on motion of Mr. Speliotis of Danvers, for a bill with the same title (House, No. 3644). July 31, 2018.

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 is hereby amended by inserting after
2 section 17O, inserted by section 1 of chapter 454 of the acts of 2016, 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 prescribed for a use approved by the federal Food and Drug Administration, including pursuant
7 to the accelerated approval provisions of section 506(c) of the Federal Food, Drug, and Cosmetic
8 Act, and as such shall not be considered experimental, investigational or unproven; and (2) the
9 drug has been ordered or prescribed consistent with the drug’s federal Food and Drug
10 Administration labeling and determined to be medically necessary by a licensed physician who
11 has thoroughly evaluated the patient and either possesses expertise in Duchenne muscular
12 dystrophy or has consulted with an expert, identified by the prescribing physician, in Duchenne
13 muscular dystrophy who has determined the drug to be medically necessary for the patient. The

14 prescribed drugs in this section shall not be subject to any greater deductible, coinsurance,
15 copayments or out-of-pocket limits than any other prescribed drug provided by the commission.
16 For purposes of this section the term “genetically targeted drug” shall mean a drug for which the
17 approved use may result in the modulation, including suppression, up-regulation, or activation,
18 of the function of a gene or its associated gene product and incorporates or utilizes non-
19 replicating nucleic acid or analogous compounds to treat one or more patient subgroups,
20 including subgroups of patients with different mutations of a gene.

21 This section shall not apply if: (1) the price of the drug increases by a percentage greater
22 than the corresponding percentage increase in the Consumer Price Index for All Urban
23 Consumers for the 2 year period beginning on the later of (i) the date this section becomes
24 effective or (ii) the date of the drug’s approval by the federal Food and Drug Administration;
25 provided, that for the purposes of this section, “price of the drug” shall mean the “wholesale
26 acquisition cost” as defined in section 1847A(c)(6)(B) of the Federal Social Security Act; or (2)
27 the manufacturer does not comply with state laws of the commonwealth, including, but not
28 limited to, transparency requirements related to drug pricing, if any.

29 SECTION 2. Chapter 118E of the General Laws is hereby amended by inserting after
30 section 10K, inserted by section 2 of chapter 120 of the acts of 2017, the following section:-

31 Section 10L. The division shall provide coverage for genetically targeted drugs for
32 Duchenne muscular dystrophy when: (1) the drug has been prescribed for a use approved by the
33 federal Food and Drug Administration, including pursuant to the accelerated approval provisions
34 of section 506(c) of the Federal Food, Drug, and Cosmetic Act, and as such shall not be
35 considered experimental, investigational or unproven; and (2) the drug has been ordered or

36 prescribed consistent with the drug’s federal Food and Drug Administration labeling and
37 determined to be medically necessary by a licensed physician who has thoroughly evaluated the
38 patient and either possesses expertise in Duchenne muscular dystrophy or has consulted with an
39 expert, identified by the prescribing physician, in Duchenne muscular dystrophy who has
40 determined the drug to be medically necessary using the division’s criteria, which shall comply
41 with the obligations under section 1927 of the Social Security Act, inclusive of the definition of
42 ‘covered outpatient drug’ pursuant to section 1927(k)(2), for the patient. The prescribed drugs in
43 this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-
44 pocket limits than any other prescribed drugs provided by the division. For purposes of this
45 section the term “genetically targeted drug” shall mean a drug for which the approved use may
46 result in the modulation, including suppression, up-regulation, or activation, of the function of a
47 gene or its associated gene product and incorporates or utilizes non-replicating nucleic acid or
48 analogous compounds to treat one or more patient subgroups, including subgroups of patients
49 with different mutations of a gene.

50 This section shall not apply if: (1) the price of the drug increases by a percentage greater
51 than the corresponding percentage increase in the Consumer Price Index for All Urban
52 Consumers for the 2 year period beginning on the later of (i) the date this section becomes
53 effective or (ii) the date of the drug’s approval by the federal Food and Drug Administration;
54 provided, that for the purposes of this section, “price of the drug” shall mean the “wholesale
55 acquisition cost” as defined in section 1847A(c)(6)(B) of the Federal Social Security Act; or (2)
56 the manufacturer does not comply with state laws of the commonwealth, including, but not
57 limited to, transparency requirements related to drug pricing, if any.

58 SECTION 3. Chapter 175 of the General Laws, as appearing in the 2016 Official Edition,
59 is hereby amended by inserting after section 47II the following section:-

60 Section 47JJ. Any individual policy of accident or sickness insurance issued pursuant to
61 this chapter shall provide coverage for genetically targeted drugs for Duchenne muscular
62 dystrophy when: (1) the drug has been prescribed for a use approved by the federal Food and
63 Drug Administration, including pursuant to the accelerated approval provisions of section 506(c)
64 of the Federal Food, Drug, and Cosmetic Act, and as such shall not be considered experimental,
65 investigational or unproven; and (2) the drug has been ordered or prescribed consistent with the
66 drug's federal Food and Drug Administration labeling and determined to be medically necessary
67 by a licensed physician who has thoroughly evaluated the patient and either possesses expertise
68 in Duchenne muscular dystrophy or has consulted with an expert, identified by the prescribing
69 physician, in Duchenne muscular dystrophy who has determined the drug to be medically
70 necessary for the patient. The prescribed drugs in this section shall not be subject to any greater
71 deductible, coinsurance, copayments or out-of-pocket limits than any other prescribed drug
72 provided by the commission. For purposes of this section the term "genetically targeted drug"
73 shall mean a drug for which the approved use may result in the modulation, including
74 suppression, up-regulation, or activation, of the function of a gene or its associated gene product
75 and incorporates or utilizes non-replicating nucleic acid or analogous compounds to treat one or
76 more patient subgroups, including subgroups of patients with different mutations of a gene.

77 This section shall not apply if: (1) the price of the drug increases by a percentage greater
78 than the corresponding percentage increase in the Consumer Price Index for All Urban
79 Consumers for the 2 year period beginning on the later of (i) the date this section becomes
80 effective or (ii) the date of the drug's approval by the federal Food and Drug Administration;

81 provided, that for the purposes of this section, “price of the drug” shall mean the “wholesale
82 acquisition cost” as defined in section 1847A(c)(6)(B) of the Federal Social Security Act; or (2)
83 the manufacturer does not comply with state laws of the commonwealth, including, but not
84 limited to, transparency requirements related to drug pricing, if any.

85 SECTION 4. Chapter 176A of the General Laws, as so appearing, is hereby amended by
86 inserting after section 8KK the following section:-

87 Section 8LL. A contract between a subscriber and the corporation under an individual
88 group or hospital service plan which is delivered, issued or renewed within the commonwealth
89 shall provide coverage for genetically targeted drugs for Duchenne muscular dystrophy when:
90 (1) the drug has been prescribed for a use approved by the federal Food and Drug
91 Administration, including pursuant to the accelerated approval provisions of section 506(c) of
92 the Federal Food, Drug, and Cosmetic Act, and as such shall not be considered experimental,
93 investigational or unproven; and (2) the drug has been ordered or prescribed consistent with the
94 drug’s federal Food and Drug Administration labeling and determined to be medically necessary
95 by a licensed physician who has thoroughly evaluated the patient and either possesses expertise
96 in Duchenne muscular dystrophy or has consulted with an expert, identified by the prescribing
97 physician, in Duchenne muscular dystrophy who has determined the drug to be medically
98 necessary for the patient. The prescribed drugs in this section shall not be subject to any greater
99 deductible, coinsurance, copayments or out-of-pocket limits than any other prescribed drug
100 provided by the commission. For purposes of this section the term “genetically targeted drug”
101 shall mean a drug for which the approved use may result in the modulation, including
102 suppression, up-regulation, or activation, of the function of a gene or its associated gene product

103 and incorporates or utilizes non-replicating nucleic acid or analogous compounds to treat one or
104 more patient subgroups, including subgroups of patients with different mutations of a gene.

105 This section shall not apply if: (1) the price of the drug increases by a percentage greater
106 than the corresponding percentage increase in the Consumer Price Index for all Urban
107 Consumers for the 2 year period beginning on the later of (i) the date this section becomes
108 effective or (ii) the date of the drug's approval by the federal Food and Drug Administration;
109 provided, that for the purposes of this section, "price of the drug" shall mean the "wholesale
110 acquisition cost" as defined in section 1847A(c)(6)(B) of the Federal Social Security Act; or (2)
111 the manufacturer does not comply with state laws of the commonwealth, including, but not
112 limited to, transparency requirements related to drug pricing, if any.

113 SECTION 5. Chapter 176B of the General Laws, as so appearing, is hereby amended by
114 inserting after section 4KK the following section:-

115 Section 4LL. Any subscription certificate under an individual or group medical service
116 agreement delivered, issued or renewed within the commonwealth shall provide coverage for
117 genetically targeted drugs for Duchenne muscular dystrophy when: (1) the drug has been
118 prescribed for a use approved by the federal Food and Drug Administration, including pursuant
119 to the accelerated approval provisions of section 506(c) of the Federal Food, Drug, and Cosmetic
120 Act, and as such shall not be considered experimental, investigational or unproven; and (2) the
121 drug has been ordered or prescribed consistent with the drug's federal Food and Drug
122 Administration labeling and determined to be medically necessary by a licensed physician who
123 has thoroughly evaluated the patient and either possesses expertise in Duchenne muscular
124 dystrophy or has consulted with an expert, identified by the prescribing physician, in Duchenne

125 muscular dystrophy who has determined the drug to be medically necessary for the patient. The
126 prescribed drugs in this section shall not be subject to any greater deductible, coinsurance,
127 copayments or out-of-pocket limits than any other prescribed drug provided by the commission.
128 For purposes of this section the term “genetically targeted drug” shall mean a drug for which the
129 approved use may result in the modulation, including suppression, up-regulation, or activation,
130 of the function of a gene or its associated gene product and incorporates or utilizes non-
131 replicating nucleic acid or analogous compounds to treat one or more patient subgroups,
132 including subgroups of patients with different mutations of a gene.

133 This section shall not apply if: (1) the price of the drug increases by a percentage greater
134 than the corresponding percentage increase in the Consumer Price Index for All Urban
135 Consumers for the 2 year period beginning on the later of (i) the date this section becomes
136 effective or (ii) the date of the drug’s approval by the federal Food and Drug Administration;
137 provided, that for the purposes of this section, “price of the drug” shall mean the “wholesale
138 acquisition cost” as defined in section 1847A(c)(6)(B) of the Federal Social Security Act; or (2)
139 the manufacturer does not comply with state laws of the commonwealth, including, but not
140 limited to, transparency requirements related to drug pricing, if any.

141 SECTION 6. Chapter 176G of the General Laws, as so appearing, is hereby amended by
142 inserting after section 4CC the following section:-

143 Section 4DD. Any individual or group health maintenance contract shall provide
144 coverage for genetically targeted drugs for Duchenne muscular dystrophy when: (1) the drug has
145 been prescribed for a use approved by the federal Food and Drug Administration, including
146 pursuant to the accelerated approval provisions of section 506(c) of the Federal Food, Drug, and

147 Cosmetic Act, and as such shall not be considered experimental, investigational or unproven; and
148 (2) the drug has been ordered or prescribed consistent with the drug’s federal Food and Drug
149 Administration labeling and determined to be medically necessary by a licensed physician who
150 has thoroughly evaluated the patient and either possesses expertise in Duchenne muscular
151 dystrophy or has consulted with an expert, identified by the prescribing physician, in Duchenne
152 muscular dystrophy who has determined the drug to be medically necessary for the patient. The
153 prescribed drugs in this section shall not be subject to any greater deductible, coinsurance,
154 copayments or out-of-pocket limits than any other prescribed drug provided by the commission.
155 For purposes of this section the term “genetically targeted drug” shall mean a drug for which the
156 approved use may result in the modulation, including suppression, up-regulation, or activation,
157 of the function of a gene or its associated gene product and incorporates or utilizes non-
158 replicating nucleic acid or analogous compounds to treat one or more patient subgroups,
159 including subgroups of patients with different mutations of a gene.

160 This section shall not apply if: (1) the price of the drug increases by a percentage greater
161 than the corresponding percentage increase in the Consumer Price Index for All Urban
162 Consumers for the 2 year period beginning on the later of (i) the date this section becomes
163 effective or (ii) the date of the drug’s approval by the federal Food and Drug Administration;
164 provided, that for the purposes of this section, “price of the drug” shall mean the “wholesale
165 acquisition cost” as defined in section 1847A(c)(6)(B) of the Federal Social Security Act; or (2)
166 the manufacturer does not comply with state laws of the commonwealth, including, but not
167 limited to, transparency requirements related to drug pricing, if any.