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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:

SECTION 1. Chapter 32A of the General Laws is hereby amended by inserting after section 17O, inserted by section 1 of chapter 454 of the acts of 2016, the following section:-

Section 17P. Any coverage offered by the commission to an active or retired employee of the commonwealth insured under the group insurance commission shall provide coverage for genetically targeted drugs for Duchenne muscular dystrophy when: (1) the drug has been prescribed for a use approved by the federal Food and Drug Administration, including pursuant to the accelerated approval provisions of section 506(c) of the Federal Food, Drug, and Cosmetic Act, and as such shall not be considered experimental, investigational or unproven; and (2) the drug has been ordered or prescribed consistent with the drug's federal Food and Drug Administration labeling and determined to be medically necessary by a licensed physician who has thoroughly evaluated the patient and either possesses expertise in Duchenne muscular dystrophy or has consulted with an expert, identified by the prescribing physician, in Duchenne muscular dystrophy who has determined the drug to be medically necessary for the patient. The

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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