HOUSE DOCKET, NO. 3869 FILED ON: 3/27/2017

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:
Edward F. Coppinger	*10th Suffolk*	*3/27/2017*

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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:

SECTION 1. Chapter 32A of the General Laws, as amended by chapter 233 of the acts of 2016, is hereby amended by inserting after section 17O 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 approved by the FDA for the prescribed use, 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 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 benefits in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-pocket limits than any other benefit 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.

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

Section 10K. The division shall provide coverage for genetically targeted drugs for Duchenne muscular dystrophy when (1) the drug has been approved by the FDA for the prescribed use, 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 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 benefits in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-pocket limits than any other benefit 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.

SECTION 3. Chapter 175 of the General Laws, as amended by chapter 233 of the acts of 2016, 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 approved by the FDA for the prescribed use, 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 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 benefits in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-pocket limits than any other benefit 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.

SECTION 4. Chapter 176A of the General Laws, as amended by chapter 233 of the acts of 2016, 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 approved by the FDA for the prescribed use, 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 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 benefits in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-pocket limits than any other benefit 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.

SECTION 5. Chapter 176B of the General Laws, as amended by chapter 233 of the acts of 2016, 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 approved by the FDA for the prescribed use, 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 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 benefits in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-pocket limits than any other benefit 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.

SECTION 6. Chapter 176G of the General Laws, as amended by chapter 233 of the acts of 2016, 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 approved by the FDA for the prescribed use, 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 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 benefits in this section shall not be subject to any greater deductible, coinsurance, copayments or out-of-

pocket limits than any other benefit 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.