BULLETIN 2019-10

TO: Commercial Health Insurers; Blue Cross Blue Shield of Massachusetts, Inc.; and Health Maintenance Organizations Offering or Renewing Insured Health Products in Massachusetts

FROM: Gary D. Anderson, Commissioner of Insurance

DATE: December 30, 2019

RE: State and Federal Requirements that Carriers Cover Certain Tobacco Cessation Products Without Consumer Cost-Sharing

The Division of Insurance ("Division") sends this Bulletin to remind carriers of certain benefit requirements for tobacco cessation aids provided for under Massachusetts law and the federal Patient Protection and Affordable Care Act ("ACA"). The Division expects carriers to be in compliance with the requirements outlined in this Bulletin as well as with any subsequent revisions and clarifications. This Bulletin updates and replaces Bulletin 2016-01, which was issued on January 19, 2016.

Massachusetts Laws Regarding Tobacco Cessation

On November 27, 2019, changes were made to Massachusetts law to enhance tobacco cessation benefits.¹ The new laws, M.G.L. c. 175, § 47LL; M.G.L. c. 176A, §8NN; M.G.L. c. 176B, §4NN; and M.G.L. c. 176G, §4FF, apply to all insured health plans that are offered to individuals residing in Massachusetts or groups that have members who reside in or have their principal workplace in Massachusetts. The laws require carriers to provide members with coverage for tobacco cessation counseling and all generic United States Food and Drug Administration-approved ("FDA-approved") tobacco cessation products.

ACA Tobacco Cessation Requirements

Preventive Services
The ACA requires coverage, with no cost-sharing, for certain evidence-based preventive items and

services given a rating of “A” or “B” by the U.S. Preventive Services Task Force (“USPSTF”). Among its recommendations, the USPSTF indicates that clinicians should screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco. It appears clear that such screening and tobacco interventions are required to be covered without cost-sharing and that plan benefits should not include any blanket benefit exclusions or limitations that apply to tobacco cessation items or services. Therefore, when prescribed by a health care provider, carriers shall not require any member cost-sharing for either tobacco cessation counseling or any of the generic FDA-approved tobacco cessation products.

The Centers for Medicare and Medicaid Services ("CMS") has also promulgated regulations that clarify that carriers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for the recommended item or service when those elements are not made clear in the USPSTF recommendations.

**Tobacco Cessation Products**

The federal Department of Health and Human Services has issued guidance that identifies the following types of tobacco cessation products as items that it believes are appropriate for smoking cessation:

- Nicotine gum,
- Nicotine patch,
- Nicotine lozenge,
- Nicotine oral or nasal spray(11,552),(68,552),
- Nicotine inhaler,
- Bupropion, and
- Varenicline.²

The Division would consider a health plan to be in compliance with the preventive care requirements of the ACA relative to tobacco cessation products if the health plan’s drug benefit includes at least one product within each of the above-noted tobacco cessation product types without cost-sharing (e.g., the health plan’s drug benefit includes coverage, without cost-sharing, for at least one nicotine gum, one nicotine patch, one nicotine lozenge, etc.).

**Tobacco Cessation Medical Management under Massachusetts Law and the ACA**

Under both Massachusetts law and the ACA, Carriers are permitted to employ reasonable managed care techniques to determine the frequency, method, treatment, or setting for the recommended item or service, provided that covered persons are always given access to at least one of the tobacco cessation products without prior authorization and provided that the managed care methods are consistent with all state and federal laws. Whenever carriers make an adverse determination that denies or limits access to a requested product based on medical necessity criteria, they must

²HHS FAQ 19, issued May 2, 2014, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html, expects coverage of all FDA-approved tobacco cessation products, including both prescription and over-the-counter medications. The FDA has approved as smoking cessation products the five tobacco replacement products and two non-nicotine medications listed.
provide all necessary notifications to patients and providers and follow all appropriate procedures for internal and external appeals.

Carriers should note that under both Massachusetts law and the ACA, tobacco cessation coverage requirements pertain to both over-the-counter and prescription products. Carriers should also be aware that, as a result of the combination of Massachusetts law and the ACA, no member cost-sharing of any kind is permitted for any tobacco cessation counseling or FDA-approved tobacco cessation products when the counseling and/or products are prescribed by a health care provider. Carriers should amend policies, evidences of coverage, formularies and/or drug brochures, or riders as necessary to ensure that insureds are given complete information about the coverage of and the cost sharing for tobacco cessation items and services.

Carriers are expected to have made any necessary changes as described above and forward for the Division’s review via the System for Electronic Rate and Form Filings (SERFF). If you have any questions about this Bulletin, please contact Niels Puetthoff at 617-521-7326 or Niels.Puetthoff@mass.gov.