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JULIANNE M. BOWLER
COMMISSIONER OF INSURANCE

Bulletin 2003-02

To: Commercial Health Insurers, Blue Cross and Blue Shield of Massachusetts, Inc., and Health Maintenance Organizations

From: Commissioner Julianne M. Bowler Julianne M Bowler

Re: Coverage for the Off-Label Uses of Prescription Drugs for the Treatment of Cancer

Date: March 7, 2003

Laws enacted in 1992 mandated certain coverage for the off-label uses of prescription drugs for the treatment of cancer: St. 1992, c. 404 §§ 1, 2, 3 and 4 which added G.L. c. 175, § 47K, c. 176A, § 8N, c. 176B, § 4N and c. 176G, § 4E. This mandate is effective for all policies, certificates, evidences of coverage and contracts that provide coverage for prescription drugs which are issued or renewed in Massachusetts. This bulletin is being issued by the Division of Insurance (Division) to clarify those source documents that would indicate off-label uses for the treatment of cancer that are covered under the mandated benefit.

Commercial health insurers, BCBSMA and HMOs that provide coverage for prescription drugs are prohibited from excluding coverage for drugs used for the treatment of cancer on the grounds that the off-label use of the drug has not been approved by the United States Food and Drug Administration for that indication, provided the drug is recognized for treatment of cancer by one of the standard reference compendia, by medical literature or by the Division, based upon the recommendations of an advisory panel established under G.L. c. 175, § 47L. In addition, medically necessary services associated with the administration of these drugs are required to be covered.

For the purpose of this law, "standard reference compendia" is defined as "(a) the United States Pharmacopoeia Drug Information; (b) the American Medical Association Drug Evaluations; or (c) the American Hospital Formulary Service Drug Information." According to the statute, "medical literature" is defined as "published scientific studies appearing in any peer-reviewed national professional journal."

The Division's advisory panel has recommended that the Division acknowledge the Association of Community Cancer Centers' *Compendia-Based Drug Bulletin,* a quarterly publication of recent changes identified by medical literature not yet published in the standard reference compendia, as a source document for the off-label uses of prescription drugs for the treatment of cancer under the mandate. Based upon the recommendations of the advisory panel and review of the submitted information, the Division hereby directs that if a drug is indicated for the treatment of cancer within the *Compendia-Based Drug Bulletin* that such drug shall be covered under the provisions of the mandate.

Any questions regarding this bulletin should be directed to the Division's Health Unit at (617) 521-7347.