COMMONWEALTH OF MASSACHUSETTS
Office of Consumer Affairs and Business Regulation
DIVISION OF INSURANCE

One South Station • Boston, MA 02110 - 2208
(617) 521-7794 • FAX (617) 521-7475
TTY/TDD (617) 521-7490
http://www.state.ma.us/doi

ARGEO PAUL CELLUCCI
GOVERNOR

JANE SWIFT
LIEUTENANT GOVERNOR

JENNIFER DAVIS CAREY
DIRECTOR, CONSUMER AFFAIRS AND BUSINESS REGULATION

LINDA RUTHARDT
COMMISSIONER OF INSURANCE

Bulletin No. 01-04

To: **Commercial Health Insurers, Blue Cross and Blue Shield of Massachusetts (BCBSMA), Health Maintenance Organizations**

From: Linda Ruthardt, Commissioner of Insurance

Re: **Human Leukocyte Antigen Testing for Certain Individuals and Patients**

Date: **February 12, 2001**

This Bulletin is to inform carriers of the enactment of St. 2000, c. 355 (Chapter 355), An Act Providing Insurance Coverage for Human Leukocyte Antigen Testing for Certain Individuals and Patients, which creates the following Massachusetts health insurance statutes: M.G.L. c. 175 §47V, c. 176A §8V, c. 176B §4V, and c. 176G §4N. Chapter 355, which becomes effective on March 28, 2001, applies to those policies delivered, issued or renewed, within or without Massachusetts, pursuant to M.G.L. c. 175, §47V and to those contracts delivered, issued or renewed, within or without Massachusetts, pursuant to M.G.L. c. 176G, §4N. Chapter 355 also applies to those policies delivered, issued or renewed, within or without Massachusetts, to Massachusetts residents and to group members having a principal place of employment within the Commonwealth pursuant to M.G.L. c. 176A and M.G.L. c. 176B. Chapter 355 does not apply to policies providing supplemental coverage to Medicare or other governmental programs, or self-funded health plans administered under the Employee Retirement Income Security Act of 1974 (ERISA). Chapter 355 applies to individual and group commercial health insurance policies, group HMO contracts and individual and group BCBSMA certificates and contracts.

Chapter 355 mandates coverage for the cost of human leukocyte antigen testing or histocompatibility locus antigen testing necessary to establish bone marrow transplant donor suitability. Such coverage will cover the costs of testing for A, B, or DR antigens, or any combination thereof, consistent with the guidelines, criteria, and rules or regulations established by the Department of Public Health.

Chapter 355 directs the Commissioner of Public Health, in collaboration with the Commissioner of Insurance, to establish guidelines, criteria, and rules or regulations regarding human leukocyte antigen testing or histocompatibility locus antigen testing. Such guidelines, criteria, and rules or regulations are to be created, as necessary, to ensure that human leukocyte

antigen testing or histocompatibility locus antigen testing conforms to medical eligibility requirements and other test protocols established by the United States Food and Drug Administration, the American Association of Blood Banks, the Joint Commission of Accreditation of Health Care Organizations, and the National Marrow Donor Program Registry.

These guidelines, criteria, and rules or regulations shall also establish the eligibility of a health care facility to conduct such tests and require such facility to obtain informed consent from test subjects prior to conducting the test and to inform the subject of the opportunity to participate in the national marrow donor program.

Finally, Chapter 355 directs the Commissioner of Public Health to convene an advisory group of medical experts to assist in decisions relative to the guidelines, criteria, and rules or regulations that may be created pursuant to §2(a) of this legislation.

Please note that the Department of Public Health expects to issue interim guidelines prior to the effective date of the new mandate regarding human leukocyte antigen testing or histocompatibility locus antigen testing necessary to establish bone marrow transplant donor suitability. The Department of Public Health also plans to convene the advisory committee within the next few weeks and to issue the necessary guidance in the month of March. Please contact the Office of Patient Protection at the Department of Public Health at (617) 624-5280 for further information on the development of these guidelines.

Please refer to the statutes, as amended, for a complete description of these new benefits. If you have any questions regarding this Bulletin, please call the Health Unit at the Division of Insurance at (617) 521-7349.