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COMMISSIONER OF INSURANCE

BULLETIN 01-16

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

From: **Linda Ruthardt, Commissioner of Insurance**
Howard K. Koh, MD, MPH, Commissioner of Public Health

Date: **November 1, 2001**

Re: **HLA Testing**

As noted in Division of Insurance Bulletin No. 2001-04, St. 2000, c. 355 (Chapter 355) mandates coverage for the cost of human leukocyte antigen testing or histocompatibility locus antigen testing (HLA testing) necessary to establish bone marrow transplant donor suitability. Such coverage is required to 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 (DPH).

Pursuant to chapter 355, DPH convened an advisory group of medical experts to assist in decisions relative to the guidelines. The guidelines established by DPH in collaboration with the Division of Insurance (DOI) are attached to this bulletin.

In addition to the guidelines, carriers should note the following:

- The mandate directs carriers to provide coverage for HLA testing. The mandate does not extend to any costs associated with recruitment of potential donors. Carriers are required to provide coverage only for the cost of the testing itself.

- Coverage for HLA testing should be consistent with the terms of the carrier's contract or evidence of coverage, with the exceptions noted in this bulletin.

- The mandate became effective on March 28, 2001 for all policies identified in Bulletin No. 2001-04. Claims for services on or after that date must be covered according to contract benefits.

- Carriers should note that if the terms of coverage require that insureds use contracted providers, *i.e.,* providers within a specified network, then carriers are not required to provide coverage for out-of-network services or services by non-contracted providers. Carriers should further note, however, that if there are currently no providers within a carrier's network that can provide the mandated service, then carriers must provide coverage for any provider at the in-network level until such time as the carrier establishes an adequate number of network providers.

- If a carrier requires that services be ordered or referred by a primary care physician, coverage for HLA testing must be provided even in the absence of any such order or referral.

Carriers are encouraged to work with the HLA donor centers and registries in their respective service areas to facilitate the process of claims submission and reimbursement. In addition, carriers are encouraged to educate their insureds about bone marrow or stem cell transplantation and the process for HLA testing and registration.

If you have any questions about insurance coverage under chapter 355, please call the Health Unit at DOI at 617-521-7349. If you have questions about the attached guidelines, please call the Office of Patient Protection at DPH at 1-800-436-7757.

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HLA Testing Guidelines

The purpose of this document is to establish guidelines pursuant to Chapter 355 of the Acts of 2000. These guidelines are being established to ensure that human leukocyte antigen testing or histocompatibility locus antigen (HLA) testing for the purpose of establishing bone marrow/stem cell transplant donor suitability conforms to specific medical eligibility, informed consent, and laboratory licensing and accreditation requirements.

Facilities that conduct HLA testing or their designees must meet the following requirements:

Medical Eligibility Criteria

- Prior to having blood drawn, each potential donor must be screened for medical eligibility using criteria established by the National Marrow Donor Program (NMDP) or equivalent criteria established by a member of the World Marrow Donor Association (WMDA).

Informed Consent

- Prior to having blood drawn, each potential donor must provide informed consent in writing. At a minimum, the informed consent must include:
  - An explanation of the medical eligibility criteria for potential stem cell donors.
  - A statement regarding the purpose of stem cell donation and the understanding that the purpose of HLA typing is to facilitate unrelated donor bone marrow or peripheral blood stem cell (PBSC) transplantation.
  - An explanation of the types of stem cell donation and the methods for collecting the stem cells, including any physical or psychological effects which may result.
  - A statement of the confidentiality of all potential donor information.
  - An explanation of the risks of venipuncture.
  - An explanation of eligibility for mandated third-party insurer coverage of HLA testing for the purposes of determining stem cell transplant donor suitability, as well as any charges for HLA typing in the absence of insurance coverage. A statement permitting the donor center to submit a claim to the insurance company must be included on this consent form or on a separate insurance form.
  - A statement that donors will not be paid for their donation.
  - Permission to register with the NMDP or with any member of the WMDA.

Laboratories that conduct HLA typing must meet the following requirements:

- Clinical Laboratory Improvement Amendments (CLIA) certification.
- Accreditation for molecular typing by the American Society for Histocompatibility and Immunogenetics (ASHI).