



## hla testing payment policy

### ***description of procedure/service***

This policy applies to payment for human leukocyte antigen (HLA) testing, also known as tissue typing or histocompatibility testing, to establish bone marrow transplant donor suitability for the purpose of enrolling as a volunteer donor in a bone marrow registry, such as the National Marrow Donor Program (NMDP). Becoming a bone marrow donor is a serious commitment. Although there is no legal obligation, a volunteer may be called upon to donate, at any time, anywhere in the world. Once a person joins a bone marrow registry, they will remain active until their 61<sup>st</sup> birthday.

There are two classes of HLA antigens. Class I HLA antigens (A, B, and C) are found in the outer membranes of cells in the human body that have a nucleus. These antigens are found in especially high concentrations on the surface of leukocytes (white blood cells). Class II HLA antigens (DR, DQ and DP) are found on B cells, activated T cells, monocytes, and macrophage cells. Antigens play an important role in the body's immune response and have also been implicated in many disease processes, particularly those with an autoimmune component. HLA testing is done to reduce the likelihood of rejection after transplant and to avoid graft-versus-host disease. The success of a transplant depends on how closely the antigens match. The NMDP sets the minimum matching levels that must be met before a donor from the NMDP Registry can be used for a transplant (although many transplant centers have their own specific requirements). These minimum requirements are based on research studies of transplant outcomes. The HLA antigens that are looked at for these minimum requirements are HLA A, B, and DR. One set of each these antigens is inherited from the mother and another set is inherited from the father. This makes a total of 6 antigens to match. For adult bone marrow transplants, the NMDP requires a match of at least 5 of these 6 HLA antigens. Except for identical twins, every person's antigen pattern is different.

HLA typing may be determined by serology or by DNA analysis. Serological HLA typing is based on response to human alloantisera collected from multiparous women or individuals who had received multiple blood transfusions. Serological typing allows for the identification of 'broad' antigens. Some broad antigens can be further identified by subtypes, which are more specific. For example, the broad HLA B15 can be 'split' into HLA B62, B63, B75, B76, and B77. Serological typing has limitations, including the availability of human alloantisera, and the inconsistency and lack of specificity of test results. Serology requires a fresh blood sample from the donor.

The discovery of a method of DNA analysis known as polymerase chain reaction (PCR) in the 1980s revolutionized the field of genetic testing. PCR has many applications, including the detection of inherited diseases, forensics and paternity testing. Using PCR, scientists can create multiple copies of DNA (known as amplification) which can then be identified using primers, probes or by direct sequencing. PCR-based DNA analysis has many advantages over serological testing because it utilizes synthetic reagents with well-defined specificity and also does not require viable cells. DNA-based testing can be done with dried, frozen or fresh blood, buccal swabs, bone marrow or any other tissue with intact DNA.

There are several methods of DNA analysis, including, but not limited to PCR-SSP (sequence specific primer), PCR-SSOP (sequence specific oligonucleotide probing), and reverse SSOP

hybridization. DNA analysis may also be performed by gene sequencing. Depending on the method used, DNA-based typing provides varying levels of specificity. Low-resolution DNA-based testing produces results similar to serological testing. Intermediate resolution is somewhat more specific, and high-resolution DNA-testing is the most specific. For example, a typical serological result: HLA-A15; a typical high-resolution DNA result: HLA B\*1504. A transition in HLA typing methodology has taken place over the past twenty years, and databases of HLA types (such as bone marrow registries) contain a mixture of serology and DNA test results.

## **policy**

FCHP covers the cost of testing for A, B, and DR antigens (tissue typing) necessary to establish a plan member's bone marrow transplant donor suitability for the purpose of enrolling in a bone marrow donor registry.

Coverage for HLA testing is mandated by Massachusetts General Law (MGL) Chapter 176G, Section 4Q and MGL Chapter 175, Section 47V, effective March 28, 2001. Pursuant to MGL, the Massachusetts Department of Public Health (DPH) established an advisory group to assist in the development of HLA testing guidelines. The HLA testing guidelines established by the MA DPH are as follows:

1. Each potential donor must meet eligibility criteria established by the NMDP or equivalent criteria established by the World Marrow Donor Association (WMDA).
2. Each potential donor must provide informed consent in writing.
3. Laboratories that conduct HLA testing must be certified and accredited to perform such testing.

An individual only needs to be tissue typed once during their lifetime. Tissue typing is similar to blood typing, in that an individual's tissue type and blood type do not change. If an individual has already been tested for a friend or family member and wants to have their results added to a donor registry, the individual can contact either the NMDP or WMDA for specific information.

Donors selected from a bone marrow registry search as potential matches for a transplant recipient will require additional testing. **Additional testing of a potential donor and any costs related to the donation are covered by the transplant recipient's insurer.** See *Transplant Payment Policy* for details on payment for services related to organ transplants.

## **benefits application**

- FCHP Direct Care / FCHP Select Care
- FCHP Independent Care
- FCHP Flex Care Direct / Select
- Fallon Senior Plan™
- FCHP MassHealth
- Major Medical
- Bill at Home/Direct Enrollment
- Fallon Preferred Care

## **coverage and reimbursement criteria**

### **Coverage criteria**

HLA typing (tissue typing) is covered for plan members who meet eligibility criteria established by the NMDP, or equivalent criteria established by the WMDA, and sign a written consent. All donors must be between 18 and 60 years of age and in good health. Some individuals may not

be eligible to donate based on their medical history. The donor registry will determine eligibility and obtain consent prior to obtaining a blood or tissue sample for testing.

The NMDP health guidelines are available at:

[http://www.marrow.org/HELP/Join\\_the\\_Registry/Med\\_Guidelines\\_Join/index.html](http://www.marrow.org/HELP/Join_the_Registry/Med_Guidelines_Join/index.html)

### **Reimbursement criteria**

For plans that require the use of network providers, FCHP will reimburse for HLA testing (tissue typing) provided by a network provider only. In the absence of an adequate number of network providers certified and accredited to perform HLA testing (in accordance with guidelines established by the MA DPH), FCHP will reimburse for HLA testing services provided by any qualified provider.

### **preauthorization guidelines**

No referral or preauthorization is required for testing of A, B and DR antigens necessary to establish a plan member's bone marrow transplant donor suitability for the purpose of enrolling in a bone marrow donor registry, such as the National Marrow Donor Program (NMDP).

### **billing/coding guidelines**

#### **CPT**

Several CPT codes in the AMA CPT Manual describe similar procedures performed in different fashions, with different levels of complexity, or associated with other related procedures. In addition, there are several component services, which have different CPT codes, which may be described in one, more comprehensive code. Only when you are unable to locate a specific code for a laboratory test in the AMA CPT Manual, it is appropriate to report it based on the method of performing the test.

The following CPT codes for HLA typing, i.e., 86812-86817, are not specific to serologic testing<sup>1</sup> and should be used to submit claims for any method of tissue typing, including, but not limited to, high resolution polymerase chain reaction typing<sup>2</sup>:

Codes	Number	Description
CPT	86813	A, B, or C, multiple antigens

<sup>1</sup> CPT Assistant, Copyright American Medical Association, Coding Consultation: Questions and Answers Pathology and Laboratory. March 2003;13(3):23.

**Question:** The CPT book contains codes for HLA typing. Are these codes restricted to use for HLA typing using a serologic specimen?

**AMA Comment:** The CPT codes for HLA typing are not specific to serologic testing; these codes may be reported when the tests are performed on any appropriate specimen source.

<sup>2</sup> CPT Assistant, Copyright American Medical Association, Coding Consultation: Questions and Answers Pathology and Laboratory. June 2006;16(6):16-17.

**Question:** From a CPT coding perspective, if a high resolution polymerase chains reaction typing of the HLA A, B, and C loci are performed with typing results for each of the two alleles on the A, B, and C loci resulting in six typing results, is it appropriate to report CPT code 86812 or CPT code 86813?

**AMA Comment:** CPT code 86812 is reported for a single determination (e.g., the relatively frequent clinical request for an HLA-B27) of either an HLA-A, HLA-B, or HLA-C test. CPT code 86813 is reported to phenotype a patient (e.g., for transplantation). The usual transplant requirements are for two loci on A, B, and C. Other determinants may also be required (e.g., DR) and are reported separately. CPT code 86813 is reported for each of the HLA-A determinations. HLA-A 2, 23; HLA-B 8, 14, would be two determinations, one for A and one for B. Therefore, if two loci at each of three HLAs (A, B, and C) are performed, it would be appropriate to report CPT code 86813 three times.

Codes	Number	Description
	86817	DR/DQ, multiple antigens

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FCHP covers the cost of A, B and DR antigen testing to establish bone marrow donor suitability. Therefore, when A, B and DR antigen testing is performed, CPT code 86813 should be submitted twice (for A and B), and CPT code 86817 should be submitted once (for DR). FCHP does not cover the cost of C and DQ antigen testing to establish bone marrow donor suitability.

Note: CPT codes 86812 and 86816 are for single antigen testing, for example, B27 or DQ6. The presence of certain antigens has been associated with an increased frequency of certain diseases. For example, HLA-B27 appears in 80-90% of patients with ankylosing spondylitis, and the DQ6 antigen is likely to be found in a person with narcolepsy. These CPT codes should not be used for tissue typing to establish bone marrow donor suitability.

### ICD-9-CM

ICD-9-CM code V70.8 (Other specified general medical examinations) should be used to report claims for tissue typing. V70.8 describes services performed for the examination of a potential donor of organ or tissue.

ICD-9-CM code V59 (Donors) or V59.3 (Bone marrow) should not be used for tissue typing. V59 or V59.3 should be used to report services for living donors who are donating body tissue to others.

### ***place of service***

This policy applies to all places of service.

### ***policy implementation***

Policy number: ADM0052

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Revision date(s):

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