



# Human Leukocyte Antigen Testing Payment Policy

## Policy

Fallon Community Health Plan (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 Human Leukocyte Antigen (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 Chapter 111, Section 218, 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 National Marrow Donor Program (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 not covered by FCHP unless FCHP is also the transplant recipient's insurer.** See the *Transplant Payment Policy* for details on payment for services related to organ transplants.

## Definitions

**Human leukocyte antigen (HLA) testing** - also known as tissue typing or histocompatibility testing, establishes 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). 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.

**HLA Antigens** - 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

there 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.

## **Benefits application**

### **Commercial**

- FCHP Direct Care/FCHP Select Care
- Commonwealth Care
- Companion Care
- FCHP MassHealth
- Major Medical
- Fallon Preferred Care

### **Senior Plan**

- Fallon Senior Plan™
- Fallon Senior Plan Preferred
- Summit ElderCare®

## **Reimbursement**

FCHP will reimburse for HLA testing (tissue typing) provided by a network provider. 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.

FCHP will reimburse only for those antigens specified in the MA state mandate and only when billed with the CPT and ICD9 codes identified in the below "Billing/coding guidelines" section of this policy.

Reimbursement is limited to testing for A, B and DR.

### **Referral/notification/preauthorization requirements**

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**

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).

The following CPT codes for HLA typing are not specific to serologic testing and should be used to submit claims for any method of tissue typing, including, but not limited to, high resolution polymerase chain reaction typing:

CPT Code	Description
86813	HLA typing: A, B, or C, multiple antigens
86817	HLA typing: DR/DQ, multiple antigens

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 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 services rendered in all settings.

### **Policy history**

Origination date: 07/01/09  
Previous revision date(s): N/A  
Connection date & details: 05/01/09 – New Policy

*This payment policy has been developed to provide information regarding general billing, coding and documentation guidelines for FCHP. Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply and this policy is not a guarantee of payment. FCHP reserves the right to apply this payment policy to all FCHP companies and subsidiaries.*