MSA MEDICAL SERVICES ADMINISTRATION

Bulletin

Michigan Department of Community Health

Bulletin Number: MSA 13-42

Distribution: Physicians, Hospitals, Medicaid Health Plans (MHP)

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Subject: Standards of Coverage and Prior Authorization Requirements for Genetic Testing

Effective: January 1, 2014

Programs Affected: Medicaid, Children's Special Health Care Services (CSHCS)

Due to the increased number of procedure codes being established for genetic testing, the Medical Services Administration (MSA) has developed written policy to inform providers of the following standards of coverage and prior authorization (PA) requirements for these tests. This policy is meant to cover all categories of genetic tests.

The standards of coverage and PA and documentation requirements listed in this bulletin apply to beneficiaries served by Fee-for-Service (FFS) Medicaid. For beneficiaries enrolled in a Medicaid Health Plan (MHP), the provider must check with the beneficiary's Plan for coverage and PA requirements.

Standards of Coverage

Whenever possible, Medicaid follows Medicare guidelines. Medicare does not cover a genetic test for a clinically affected individual for purposes of medical research, family planning, disease risk assessment of other family members, or when the treatment and surveillance of the beneficiary will not be affected or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

A. Genetic testing is considered a covered benefit when it is medically necessary to establish a molecular diagnosis and treatment of a genetic disease and all of the following are met:

- The testing must be ordered by a physician (M.D. or D.O.), who is an enrolled provider.
- The beneficiary has documented clinical features symptomatic of a condition or disease, or is at risk of inheriting the disease based upon personal history, family history, documentation of a genetic mutation and/or ethnic background.
- Following history, physical examination, pedigree analysis, and completion of conventional diagnostic testing, a definitive diagnosis remains uncertain and a genetic diagnosis is suspected.
- The test results will be used to significantly alter the management or treatment of the disease.
- If applicable, the testing method is a Food and Drug Administration (FDA)-approved method for the identification of a specific genetically linked inheritable disease as evidenced by the following measures:
    - The genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of the disease;
    - The analytical and clinical validity of the test must be established;
    - The observations must be independently replicated and subject to peer review;
    - The clinical testing laboratory must be an enrolled provider, who is properly certified by Clinical Laboratory Improvement Amendments (CLIA).

Testing is allowed once during the member's lifetime per disease for diagnostic purposes. If medically necessary, and on a case-by-case basis, PA may be requested to allow for exceptions to this restriction.

Providers must follow state law (Public Act 368 of 1978, Section 333.17020 Genetic test; informed consent) regarding informed consent for predictive genetic testing. This includes any statutory requirements for pre or post testing genetic counseling. There must be made available, upon request, documentation of pretesting informed consent provided before testing. This documentation must include the limitations of the test, possible outcomes, and methods for communicating and maintaining confidentiality of results.

B. Genetic Testing is not considered a covered benefit for:

- Criteria other than those outlined under the Standards of Coverage section above.
- Testing to confirm a diagnosis or disorder that can be diagnosed by conventional diagnostic methods.
- Testing for conditions or purposes where the test results would not directly influence the management or treatment of the disease or condition (e.g., a disease without known treatment).
- Testing for informational purposes or management of a beneficiary's family member.
- Confirmatory testing for validation of laboratory results.
- Screening for investigational or research purposes.
- Minors under the age of 18 for adult onset conditions that have no preventative or therapeutic treatments.
- Testing that has not been performed in a CLIA certified laboratory.
- The sole purpose of family planning counseling and infertility services.

Prior Authorization Requirements and Documentation

For genetic testing that requires PA, the following documentation must be submitted prior to the testing being performed:

- Indication for the test.
- Clinical notes that clearly detail the beneficiary's related signs and symptoms, including relevant family history. A family pedigree analysis must be made available upon request.
- Other related testing or clinical findings in the beneficiary or family member.
- Documentation supporting that the test results will be used to significantly alter the management or treatment of the disease.
- The name and National Provider Identifier (NPI) number of the laboratory performing the test.

Manual Maintenance

Retain this bulletin until the information has been incorporated into the Michigan Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Community Health, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mail at ProviderSupport@michigan.gov. When you submit an e-mail be sure to include your name, affiliation, and phone number so you may be contacted if necessary. Providers may phone toll-free 1-800-292-2550.

Approved

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