Pharmacogenetics

This drafted policy is open for a two-week public comment period. This box is not part of the drafted policy language itself, and is intended for use only during the comment period as a means to provide readers with a summarized list of the new policy.

The policy:

- Covers testing for cytochrome 2D6, 2C9, and 2C19
- Limits 2D6 testing (procedure code 81226) to Huntington's disease and Gaucher disease type 1
- Requires prior authorization (PA) for 2C19 (procedure code 81225) and 2C9 (procedure code 81227) testing and defines the conditions under which the test is considered medically necessary
- Restricts each of the three tests to once in life time for the same client, but allows case-by-case exceptions through prior authorization and Medical Directors' review
- Limits service settings to: Independent Laboratory/Privately Owned Lab with or without physician Involvement
- Emphasizes the excluded conditions and drugs/treatments for these three tests

IMPORTANT:
The Healthcare Common Procedure Coding System (HCPCS)/Current Procedural Terminology (CPT) codes included in this policy are subject to National Correct Coding Initiative (NCCI) relationships guidelines. According to federal law, Texas Medicaid and the CSHCN Services Program may impose stricter limitations than are imposed by the Centers for Medicare and Medicaid Services (CMS). Additional restrictions made by Texas Medicaid and the CSHCN Services Program may be outlined in the Texas Medicaid and CSHCN Services Program medical policies. Providers should refer to the Centers for Medicare & Medicaid Services (CMS) NCCI web page at www.cms.gov/MedicaidNCCICoding/ for correct coding guidelines and specific applicable code combinations.

In instances when Texas Medicaid or CSHCN Services Program medical policy is more restrictive than NCCI MUE guidance, Texas Medicaid or CSHCN Services Program medical policy prevails.

Texas Medicaid managed care organizations (MCOs) must provide all medically necessary, Medicaid-covered services to eligible clients. Administrative procedures such as prior authorization, pre-certification, referrals, and claims/encounter data filing may differ from traditional Medicaid (fee-for-service) and from MCO to MCO. Providers should contact the client's specific MCO for details.

Note: Under the Early Periodic Screening Diagnostic, and Treatment (EPSDT) regulation, Section 1905(r) of the Social Security Act mandates that all Medicaid eligible beneficiaries who are birth through 20 years of age receive medically necessary services to treat, correct and ameliorate illnesses and conditions identified if the service is covered in the state's Medicaid plan or is an optional Medicaid service. It is the

Responsibility of the state to determine medical necessity on a case specific basis. No arbitrary limitations on services are allowed (e.g. one pair of eyeglasses or 10 therapy sessions per year) if determined to be medically necessary.

- Services not covered under this section include:
- Experimental or investigational treatment;
- Services or items not generally accepted as effective and/or not within the normal course and duration of treatment;
- Services for the caregiver or provider convenience.

All EPSDT requirements must be adhered to for beneficiaries who receive services under managed care arrangements.

Statement of Benefits

1 Pharmacogenetics of p450 (CYP450) may be a benefit of Texas Medicaid.

2 Pharmacogenetics encompasses the use of information encoded in DNA to help predict responses to medicines and thereby enhance the effectiveness and safety of medicines for individual clients. The cytochrome p450 (CYP450) family is a major subset of all drug metabolizing enzymes that applies to the pharmacogenetics technique.

3 The CYP450 superfamily is a large group of enzymes with an essential role in drug metabolism through the liver's enzyme system that is necessary for the detoxification of foreign chemicals and the metabolism of drugs. The genetic variance encoded in DNA of these enzymes for individuals can be clinically significant in the development of drug-drug interactions that may cause unanticipated adverse reactions or therapeutic failures.

4 Texas Medicaid covers testing of three enzymes: CYP2C19 (procedure code 81225), CYP2D6 (procedure code 81226), and CYP2C9 (procedure code 81227).

Policy Overview/Scope

5 Pharmacogenetics testing of CYP450 metabolic pathway may be considered medically necessary only if the results of such testing are necessary to differentiate between treatment options.

6 The use of pharmacogenetics may be considered medically necessary, once in a lifetime, to determine effective response to drug therapy for the following:

6.1 The pharmacogenetics testing of polymorphic 2D6, when using procedure code 81226, may be considered medically necessary when the following conditions are met:

6.1.1.1 The client has never received genetic testing of the 2D6 alleles, and

6.1.1.2 The Client has a diagnosis of Gaucher disease type 1, and

6.1.1.3 Treatment with eliglustat (Cerdelga®) is being considered;

Or

6.1.2.1 The client has never received genetic testing of the 2D6 alleles, and

6.1.2.2 The client has a diagnosis of Huntington's disease, and

6.1.2.3 Treatment with tetrabenzine (Xenazine®) is being considered in a dosage greater than 50mg per day.

6.2 The pharmacogenetics testing of polymorphic 2C19, when using procedure code 81225, may be a benefit for clopidogrel treatment when medically necessary, and requires prior authorization.

6.3 The pharmacogenetics testing of polymorphic 2C9, when using procedure code 81227, may be a benefit for warfarin treatment when medically necessary, and requires authorization.

Authorization Requirements

Medical Policy Prior Authorization Information

7 Prior authorization is required for pharmacogenetic testing of polymorphic 2C19 when using procedure code 81225. The test may be considered medically necessary when the following conditions are met:

7.1 The client has never received genetic testing of the 2C19 alleles, and

7.2 The client is currently prescribed with clopidogrel treatment, or the use of clopidogrel treatment is being proposed, and

7.3 The clopidogrel treatment is to be used for or is being used for one of the following diseases or conditions:

7.3.1 ST elevated and non-ST elevated myocardial infarction (STEMI and NSTEMI)

7.3.2 Subsequent STEMI and NSTEMI

7.3.3 Dressler's syndrome

7.3.4 Unstable angina

7.3.5 Cerebral infarction due to embolism of cerebral arteries

7.3.6 Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction

7.3.7 Peripheral vascular disease

8 Prior authorization is required for pharmacogenetic testing of polymorphic 2C9 when using procedure code 81227. The test may be considered medically necessary when the following conditions are met:

8.1 The client has never received genetic testing of the 2C9 alleles, and

8.2 Treatment with warfarin (VKAs-vitamin K antagonists) is being considered or client is currently receiving Warfarin treatment, and

8.3 The Warfarin treatment is to be used for or is being used for one of the following diseases or conditions:

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8.3.1 Irregular heartbeat

8.3.2 Prosthetic (replacement or mechanical) heart valves

8.3.3 Myocardial Infarction

8.3.4 Risk of venous thrombosis (swelling and blood clot in a vein)

8.3.5 Risk of pulmonary embolism (a blood clot in the lung)

9 Prior authorization is not required when the initial claim is submitted for procedure code 81226.

10 Each of the three pharmacogenetic testing procedure codes 81225, 81226, and 81227 is limited to once in a lifetime. Reimbursement requests to repeat the same test may be considered through prior authorization on a case-by-case basis by Medical Director review when following criteria are met for clients who:

10.1 Have Huntington's disease and a history of procedure 2D6 testing (procedure code 81226) of eliglustat treatment and are requesting 2D6 testing for tetrabenzine treatment.

10.2 Have Gaucher disease and a history of procedure 2D6 testing (procedure code 81226) of tetrabenzine treatment 2D6 testing for eliglustat treatment.

10.3 Are unable to provide the previous test results. Every reasonable effort should be made and documentation of the efforts taken to obtain the test results from the client's pharmacogenetics physician or testing laboratory who ordered/conducted the previous tests should be submitted with the prior authorization request.

11 To facilitate a determination of medical necessity and avoid unnecessary denials, the provider must submit the proposed or current treatment plan including drug name, dosage, and frequency that support the accurate medical necessity of the services requested. The required information can be either captured in the Special Medical Prior Authorization (SMPA) form (see Line13), statement of medical necessity field in Section C, or submitted separately with the SMPA form.

12 For prior authorization, a Special Medical Prior Authorization (SMPA) form, including the Laboratory TPI field in section D, must be completed and signed, dated, and submitted by the prescribing or ordering provider. Prior authorization requests from laboratories will not be processed.

NOTE: The provider is then expected to share the authorization number with the lab submitting the claim.

13 Prior authorization requests may be submitted to the TMHP Prior Authorization Department via mail, fax, or the electronic portal. Prescribing or ordering providers may sign prior authorization forms and supporting documentation using electronic or wet signatures. For additional information about electronic signatures, please refer to the 'Electronic Signatures in Prior Authorizations' medical policy.

Reimbursement/Billing Guidelines

14 The following procedure codes may be reimbursed for pharmacogenetics of p450 services:

Table A: Procedure Codes for pharmacogenetics of p450 Services

Service Category	Procedure Codes	Additional Information
Laboratory	81225	Prior authorization required for the procedure.
Laboratory	81226	Restricted to diagnoses G10 and E75.22.
Laboratory	81227	Prior authorization required for the procedure.

15 Reimbursement for procedure code 81226 is limited to the following diagnosis codes::

Table B: Diagnosis Codes for pharmacogenetics of p450 Services

Service	Diagnosis Codes
Laboratory	G10
Laboratory	E75.22

Documentation Requirements

16 In addition to documentation requirements outlined in the "Authorization Requirements" section of this policy, the following requirements apply:

16.1 All services outlined in this policy are subject to retrospective review to ensure that the documentation in the client's medical record supports the medical necessity of the service(s) provided.

16.2 The following documentation must be maintained in the client's medical record and is subject to retrospective review:

16.2.1 Documents to support patient diagnoses.

16.2.2 Documents to support patient treatment plans.

Exclusions

17 The pharmacogenetics tests of polymorphisms in p450 superfamily other than 2D6, 2C19, and 2C9, for the purpose of aiding in the choice of drug or dose to increase efficacy and/or avoid toxicity is considered experimental, investigational and is not covered.

18 The following conditions and drugs/treatments using any of 2D6, 2C19, or 2C9 tests are not benefits of Texas Medicaid Services Program:

18.1 Opioid pain medicines (codeine, oxycodone, hydrocodone, tramadol, fentanyl, and methadone).

18.2 Selective serotonin reuptake inhibitors (SSRI).

18.3 Selective norepinephrine reuptake inhibitors (SNRIs).

18.4 Beta Blockers.

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18.5 Selective tricyclic antidepressants.

18.6 Selective antipsychotic drugs.

18.7 Efavirenz and other antiretroviral therapies for HIV (human immunodeficiency virus) infection.

18.8 Immunosuppressant for organ transplantation.

18.9 Aricept® (donepezil) for individuals with Alzheimer's disease.

18.10 p450 polymorphisms test panels that include, but not limited to 2C19, 2D6, and 2C9, for any drug response

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