Pharmacogenetics Benefit Guidelines to Change for Texas Medicaid Beginning August 1, 2017

Information posted June 22, 2017

**Note:** 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.

Effective for dates of service on or after August 1, 2017, benefit guidelines for pharmacogenetics will change for Texas Medicaid.

**Overview of Benefits**

Major highlights of this medical benefit policy include the following:

- Medically necessary criteria
- Prior authorization requirements
- Noncovered services

Pharmacogenetic testing will only be a benefit as follows:

<table>
<thead>
<tr>
<th>Procedure Codes</th>
<th>Payable Provider Type</th>
<th>Limitation</th>
</tr>
</thead>
<tbody>
<tr>
<td>81225, 81226, 81227</td>
<td>Independent laboratory</td>
<td>Once per lifetime, per client</td>
</tr>
</tbody>
</table>

**Medically Necessary Criteria**

Pharmacogenetic testing of cytochrome p450 (CYP450) metabolic pathway may be considered medically necessary only if the results of the testing are necessary to differentiate between treatment options.

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

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Drug Treatment</th>
<th>Diagnosis Restriction</th>
<th>Prior Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>81225</td>
<td>Clopidogrel</td>
<td></td>
<td>Required</td>
</tr>
<tr>
<td>81226</td>
<td>Eliglustat</td>
<td>E7522</td>
<td>Required for repeat testing</td>
</tr>
<tr>
<td></td>
<td>Tetrabenazine in a dosage greater than 50mg per day</td>
<td>G10</td>
<td></td>
</tr>
<tr>
<td>81227</td>
<td>Warfarin</td>
<td></td>
<td>Required</td>
</tr>
</tbody>
</table>

**Prior Authorization Requirements**

Prior authorization requests must be submitted on the Special Medical Prior Authorization (SMPA) Request Form. The form must be completed, signed, dated, and submitted by the prescribing or ordering provider.
Prior authorization requests from laboratories will not be processed. The requesting provider must share the prior authorization number with the laboratory submitting the claim.

The prior authorization request must include the following:

- Laboratory TPI in section D of the SMPA Request Form
- Proposed or current treatment plan, including the drug name, dosage, and frequency that support the medical necessity of the service requested
  - This information may be documented in the “Statement of medical necessity” field under Section C of the SMPA Request Form or submitted separately with the prior authorization request.
- For prior authorization of procedure code 81225, the ordering provider must include a statement on the SMPA Request Form attesting that the client has never received clopidogrel treatment.
- For prior authorization of procedure code 81227, the ordering provider must include a statement on the SMPA Request Form attesting that the client has never received warfarin treatment.

**Procedure Code 81225 - Testing of Polymorphic 2C19**

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

- The client has never received genetic testing of the 2C19 alleles.
- The client has never received clopidogrel treatment.
- The clopidogrel treatment will be used for one of the following diseases or conditions:
  - ST elevated and non-ST elevated myocardial infarction (STEMI and NSTEMI)
  - Subsequent STEMI and NSTEMI
  - Dressler's syndrome
  - Unstable angina
  - Cerebral infarction due to embolism of cerebral arteries
  - Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
  - Peripheral vascular disease, including unspecified

**Procedure Code 81226 - Testing of Polymorphic 2D6**

Prior authorization is not required for the initial pharmacogenetic testing of polymorphic 2D6 that is performed on a client.

Prior authorization is required for repeat testing.

**Procedure Code 81227 - Testing of Polymorphic 2C9**

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

- The client has never received genetic testing of the 2C9 alleles
The client has never received warfarin (vitamin K antagonists) treatment

The Warfarin treatment will be used for one of the following diseases or conditions:
  o Irregular heartbeat or rhythm
  o Prosthetic (replacement or mechanical) heart valves
  o Myocardial infarction
  o Risk of venous thrombosis (swelling and blood clot in a vein)
  o Risk of pulmonary embolism (a blood clot in the lung)

Repeat Testing

Prior authorization requests to repeat the same test (procedure code 81225, 81226, or 81227) will be reviewed by the medical director when one of the following criteria is met:

  • Previous test results are unavailable. Every reasonable effort must be made to obtain the test results from the client's provider or laboratory who previously ordered or conducted testing. Documentation of these efforts must be submitted with the prior authorization request.
  • The client has Huntington's disease and a history of pharmacogenetic testing of 2D6 (procedure code 81226) for tetrabenazine treatment, and the new request is for the same testing of 2D6 but for eliglustat to treat Gaucher disease type 1.
  • The client has Gaucher disease type 1 and a history of pharmacogenetic testing of 2D6 (procedure code 81226) for eliglustat treatment, and the new request is for the same testing of 2D6 but for tetrabenazine to treat Huntington's disease.

Noncovered Services

The following services are not a benefit of Texas Medicaid:

  • Pharmacogenetics tests of polymorphisms in a p450 superfamily other than 2D6, 2C19, or 2C9, which are performed for the purpose of aiding in the choice of drug or dose to increase efficacy or avoid toxicity, as they are considered experimental and investigational
  • The routine clinical use of genetic testing to screen patients treated with clopidogrel who are undergoing percutaneous coronary intervention (PCI)
  • The use of any of the 2D6, 2C19, or 2C9 tests for the following conditions, drugs, or treatments:
    o Opioid pain medicines (codeine, oxycodone, hydrocodone, tramadol, fentanyl, and methadone)
    o Selective serotonin reuptake inhibitors (SSRIs)
    o Selective norepinephrine reuptake inhibitors (SNRIs)
    o Beta blockers
    o Selective tricyclic antidepressants
    o Selective antipsychotic drugs
- Efavirenz and other antiretroviral therapies for human immunodeficiency virus (HIV) infection
- Immunosuppressants for organ transplantation
- Aricept® (donepezil) for individuals with Alzheimer’s disease
- p450 polymorphisms test panels for any of the 3 alleles 2C19, 2D6, or 2C9

For more information, call the TMHP Contact Center at 1-800-925-9126.