Clinical Policy: Pharmacogenetic Testing
Reference Number: TX.CP.MP.528
Last Review Date: 07/20

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Pharmacogenetic testing can determine how a member’s genetic factors may affect his/her response to a specific medication. The goals of such testing are to reduce the risk of an adverse medication reaction and/or provide information regarding potential efficacy of a particular drug.

It is the policy of Superior HealthPlan that pharmacogenetic testing may be considered medically necessary if the results of the testing can differentiate between treatment options. This policy applies to the following products: STAR, STAR+PLUS, STAR Health, STAR Kids, MMP, and CHIP.

Policy/Criteria
I. Pharmacogenetic testing for CYP2C19 polymorphisms is medically necessary when a member has been prescribed clopidogrel for one of the following indications:
   A. ST elevated and non-ST elevated myocardial infarction (STEMI and NSTEMI)
   B. Subsequent STEMI and NSTEMI
   C. Dressler’s syndrome
   D. Unstable angina
   E. Cerebral infarction due to embolism of cerebral arteries
   F. Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction
   G. Peripheral vascular disease

II. Pharmacogenetic testing for CYP2D6 polymorphisms is medically necessary when a member has one of the following indications:
   A. Has Huntington’s disease and treatment with tetrabenazine is being considered at a dosage greater than 50 mg per day OR
   B. Has Gaucher disease type 1 and treatment with eliglustat is being considered

III. Pharmacogenetic testing for CYP2C9 polymorphisms is medically necessary when a member has been prescribed warfarin for one of the following indications:
   A. Irregular heartbeat or rhythm
   B. Prosthetic heart valve
   C. Myocardial infarction
   D. Venous thrombosis
   E. Pulmonary embolism

IV. The following services are not a benefit of Texas Medicaid because they are considered experimental and investigational and therefore are not medically necessary:
CLINICAL POLICY
Pharmacogenetic Testing

A. Pharmacogenetic testing for polymorphisms in the p450 superfamily other than for CYP2D6, CYP2C19, or CYP2C9

B. The routine clinical use of genetic testing to screen patients treated with clopidogrel who are undergoing percutaneous coronary intervention

C. CYP2D6, CYP2C19, or CYP2C9 polymorphism testing for predicting response to:
   1. Beta blockers
   2. Donepezil
   3. Efavirenz and other antiretroviral therapies for human immunodeficiency virus (HIV) infection
   4. Immunosuppressants for organ transplantation
   5. Opioid pain medicines (codeine, oxycodone, hydrocodone, tramadol, fentanyl, and methadone)
   6. Selective antipsychotic drugs
   7. Selective norepinephrine reuptake inhibitors
   8. Selective serotonin reuptake inhibitors
   9. Selective tricyclic antidepressants

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81225</td>
<td>CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19) (eg, drug metabolism), gene analysis, common variants</td>
</tr>
<tr>
<td>81226</td>
<td>CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism), gene analysis, common variants</td>
</tr>
<tr>
<td>81227</td>
<td>CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg, drug metabolism), gene analysis, common variants</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>
**Clinical Policy**

**Pharmacogenetic Testing**

**ICD-10-CM Diagnosis Codes that Support Coverage Criteria**

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy</td>
<td>08/17</td>
<td>08/17</td>
</tr>
<tr>
<td>Annual Review. Updated review date, references and signatories. Removed code descriptors.</td>
<td>07/18</td>
<td>07/18</td>
</tr>
<tr>
<td>Updated to new template from TX.UM.28 (TX.CP.MP.528 nomenclature implementation 09/14/19). Under section II A. added ‘Has Huntington’s disease’. Updated references.</td>
<td>07/19</td>
<td>07/19</td>
</tr>
<tr>
<td>Updated References. Annual Review.</td>
<td>07/20</td>
<td>07/20</td>
</tr>
</tbody>
</table>

**References**


**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.
CLINICAL POLICY
Pharmacogenetic Testing
This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

©2020 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.