

Policy: MP376

Section: Medical Policy

Subject: Gene Testing to Predict Opioid Use Disorder Risk

Applicable Lines of Business

Commercial	x	CHIP	x
Medicare	x	ACA	x
Medicaid	x		

I. Policy: Gene Testing to Predict Opioid Use Disorder Risk

II. Purpose/Objective: To provide a policy of coverage regarding Gene Testing to Predict Opioid Use Disorder Risk

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking

into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

AvertD™ is a prescription, qualitative genotyping test used to detect and identify 15 genetic polymorphisms that may be associated with an elevated genetic risk for developing Opioid Use Disorder (OUD). The test utilizes DNA isolated from a buccal swab sample. AvertD™ may be used as part of a complete clinical evaluation and risk assessment of a member to identify those who may be at elevated risk of developing OUD. Results of the test are not intended to be used alone to make any decisions regarding treatment, and results from this test do not mean that the member will or will not develop OUD.

INDICATIONS:

AvertD™ genetic testing may be considered medically necessary when all of the following criteria are met:

- The member is age 18 and older and has not previously received oral opioids; and
- Is planned to undergo a surgery, procedure or intervention where oral opioid pain control is being considered; and
- Testing is ordered prior to the member receiving a first prescription of oral opioids for 4-30 days for acute pain; and
- The ordering provider has completed the mandatory education and training (SOLVD Health's AvertD HCP Education program) prior to ordering the test.

LIMITATIONS:

Testing is limited to once per lifetime.

EXCLUSIONS:

Testing is not indicated in members who have previously taken prescription oral opioids. Its use is therefore **Unproven** and **NOT COVERED** in that scenario.

Testing is not indicated to be used in members being treated for chronic pain disorder. It is **Unproven** and **NOT COVERED** in members being treated for chronic pain.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

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0078U Pain management (opioid-use disorder) genotyping panel, 16 common variants (i.e., ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Health Plan Technology Assessment Committee. AvertD April 2024

Donaldson K, Cardamone D, Genovese M, Garbely J, Demers L. Clinical Performance of a Gene-Based Machine Learning Classifier in Assessing Risk of Developing OUD in Subjects Taking Oral Opioids: A Prospective Observational Study. *Annals of Clinical & Laboratory Science* 2021;51(4):1-10

Mallow PJ, Belk KW. Cost–utility analysis of single nucleotide polymorphism panel-based machine learning algorithm to predict risk of opioid use disorder. *J. Comp. Eff. Res.* 2021 (Epub ahead of print)

Klimas J, Gorfinkel L, Fairbairn N, et al., Strategies to Identify Patient Risks of Prescription Opioid Addiction When Initiating Opioids for Pain: A Systematic Review. *JAMA Netw Open.* 2019;2(5):e193365.

American Pharmacists Association, APhA Policy Manual, Use of Genomic Data Within Pharmacy Practice (2023), <https://aphanet.pharmacist.com/policy-manual>

CDC, CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States (Nov. 4, 2022), <https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm>.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/24

Revised:

Reviewed:

CMS UM Oversight Committee Approval: 7/24

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.