

| | | |
|--|---|----------------|
| MEDICAL POLICY | Organic Acid Testing | |
| Effective Date: 10/1/2020  <div style="text-align: right;">10/1/2020</div> | Section: LAB | Policy No: 295 |
| | Technology Assessment Committee Approved Date: 8/16 Medical Policy Committee Approved Date: 6/15; 3/16; 10/17; 10/18; 8/19; 9/2020 | |
| Medical Officer | Date | |

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

| |
|--|
| <p>POLICY CRITERIA</p> <ul style="list-style-type: none"> I. Screening for organic acid disorders may be considered medically necessary and covered for symptomatic newborns and infants up to 1 year of age. II. Organic acid testing is considered not medically necessary and is not covered when the criterion (I.) above is not met, including but not limited to testing for the following conditions: <ul style="list-style-type: none"> A. Fatigue B. Sleep abnormalities C. Mood changes D. Blood sugar dysregulation E. Weight gain F. Nausea G. Multiple chemical sensitivity H. Bloating |
|--|

- I. Distention
 - J. Joint pain
 - K. Gas
 - L. Reflux
 - M. Autoimmune disorders
 - N. Dermatitis
 - O. Depression
 - P. Anxiety
 - Q. Cancer
 - R. Inflammation
 - S. Headaches
 - T. Early aging
- III. Panels that include multiple organic acids are considered **not medically necessary and are not covered**, including but not limited to the following:
- A. Genova Diagnostics® Metabolic Analysis Profile (Organic Acids)
 - B. Genova Diagnostics® Organix® Basic Profile
 - C. Genova Diagnostics® Organix® Comprehensive Profile
 - D. Genova Diagnostics® Organix® Dysbiosis Profile
 - E. The Great Plains Laboratory, Inc. Organic Acid Test

BILLING GUIDELINES

Please bill the most appropriate unlisted code for organic acid testing panels. If any of the following codes are billed individually as part of an organic acid testing panel, this is considered unbundling and the claim will deny as incorrect coding:

| | | |
|-------|-------|-------|
| 82139 | 82726 | 83921 |
| 82239 | 83150 | 84210 |
| 82507 | 83497 | 84392 |
| 82570 | 83605 | 84585 |
| 82725 | 83919 | |

CPT CODES

| All Lines of Business | |
|--|---|
| Unlisted Codes | |
| All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered . | |
| 81599 | Unlisted multianalyte assay with algorithmic analysis |

DESCRIPTION

Organic Acids

Organic acids are metabolic intermediates that are produced in pathways of central energy production, detoxification, neurotransmitter breakdown, or intestinal microbial activity.¹

Organic Acid Disorders

Organic acid disorders are rare inherited conditions that cause a buildup of toxic organic acid intermediates.^{2,3} This is due to enzyme deficiencies that limit the body's ability to breakdown certain amino acids. Organic academia, is a class of inborn errors of metabolism that presents itself in the first week of life.

Symptoms can include a lack of appetite, vomiting, seizures, lack of energy, muscle irritability, and low body temperature. Illness can be triggered by infections or by fasting. If left untreated, organic acid disorders may cause serious medical problems including brain damage, coma and even death.

Organic Acid Testing

Organic acid tests are used to diagnose organic acid disorders.^{2,3} They are also being utilized to identify metabolic blocks or problems with detoxification, gut dysbiosis (microbial imbalance on or inside the body), or oxidative stress.¹ Tests used for this purpose are believed to provide a view into the body's cellular metabolic processes and the efficiency of metabolic function. It is believed that identifying metabolic blocks that can be treated nutritionally allows individual tailoring of interventions that maximize patient responses and lead to improved patient outcomes.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of organic acid testing to diagnose metabolic disorders in adults. Organic acid testing in newborns is considered standard of care and is encompassed in expanded newborn screening performed within the first week of life.² Therefore, a review of evidence was not conducted regarding organic acid testing in newborns. Below is a summary of the available evidence identified through June of 2020.

There was minimal information or clinical studies on the validity and utility of organic acid testing to diagnose metabolic disorders in adults. Therefore, this testing is considered not medically necessary. Studies of clinical and analytical validity, as well as clinical utility would be required to assess the medical necessity of organic acid testing to diagnose metabolic disorders in adults.

CLINICAL PRACTICE GUIDELINES

No evidence-based clinical practice guidelines were identified which address the use of organic acid testing to diagnose metabolic disorders in adults.

CENTERS FOR MEDICARE & MEDICAID

As of 7/29/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses organic acid testing for organic acid disorders in adults.

POLICY SUMMARY

To date, there is a paucity of evidence evaluating organic acid testing for the diagnosis of metabolic disorders in adults. Additional studies of clinical and analytical validity, as well as clinical utility are required to assess the medical necessity of this diagnostic service. There are no clinical practice guidelines which address the use of organic acid testing to diagnose metabolic disorders in adults.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES

1. Genova Diagnostcs Organix® Comprehensive Profile <https://www.gdx.net/product/organix-comprehensive-profile-metabolic-function-test-urine>. Accessed 7/29/2020
2. Olaf A Bodamer M, PhD, FAAP, FACMG. UpToDate: Organic acidemias: An overview and specific defects. https://www.uptodate.com/contents/organic-acidemias-an-overview-and-specific-defects?search=organic%20acid%20disorder&source=search_result&selectedTitle=2~42&usage_type=default&display_rank=2. Published 2019. Updated 2/16/2019. Accessed 7/29/2020.
3. V Reid Sutton M. UpToDate: Inborn errors of metabolism: Identifying the specific disorder. https://www.uptodate.com/contents/inborn-errors-of-metabolism-identifying-the-specific-disorder?search=organic%20acid%20disorder&source=search_result&selectedTitle=1~42&usage_type=default&display_rank=1. Published 2019. Updated 5/6/2019. Accessed 7/29/2020.