Organic Acid Testing

MEDICAL POLICY NUMBER: 254

Effective Date: 12/1/2025

Last Review Date: 10/2025

Next Annual Review: 10/2026

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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

Organic Acid Testing: Diagnostic Guideline Note D1

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Screening for organic acid disorders may be considered **medically necessary** in any of the following situations:
   a. newborns and infants up to 1 year of age, or
   b. Members with metabolic disorders (see Billing Guidelines), or
   c. Methylmalonic acid testing for suspicion of B12 deficiency

II. Organic acid testing is considered **not medically necessary** when the criterion (I.) above is not met, including but not limited to testing for the following conditions:

   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**, 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

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

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.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 is 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 September 2025.

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

American College of Medical Genetics and Genomics (ACMG)

In 2018, the ACMG published clinical practice guidelines regarding the laboratory analysis of organic acids.[4] Authors stated that disorders that may be identified or suggested through abnormal urine organic acid analysis include the classic organic acidemias due to inborn errors of amino acid metabolism, methylmalonic acidemia, propionic acidemia, glutaric acidemia type I, as well as other amino acid disorders, tyrosinemia type I, alkaptonuria, 3-methylglutaconic aciduria type I, maple syrup urine disease.

EVIDENCE SUMMARY

Organic acid testing is used for a wide range of clinical applications, though well-designed clinical studies have yet to show that organic acid testing improves overall health outcomes when used for diagnosing metabolic disorders in adults. However, clinical practice guidelines recommend the use of organic acid testing to diagnose metabolic disorders in adults. Therefore, organic acid testing is considered not medically necessary except for use in newborns and in patients with suspected metabolic disorders.

HEALTH EQUITY CONSIDERATIONS

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

BILLING GUIDELINES AND CODING

Per Coding Policy 30.0, when no specific CPT or HCPCS code exists for the panel, the provider is required to bill using an unlisted code. It is not appropriate for the provider to bill any of the tests in a panel separately as if they were performed individually. This is a misrepresentation of services performed and is not appropriate based on either CPT or CMS guidelines. In a "Healthcare Fraud Prevention Partnership" white paper published in May 2018, CMS identified unbundling of lab panels as an example of fraudulent billing.

Excluding newborns (12 months of age or younger), CPT codes for organic acid testing (83918, 83919, 83921) may be considered medically necessary only when billed with a diagnosis code in the range of E00-E89, or any of the following: K909, Z8639, Z13228, Z8349, G9341. When diagnosis codes other than these are billed, the below CPT codes will deny as not medically necessary.

CPT 83921 may be used for methylmalonic acid testing for potential B12 deficiency (D51.0, D51.1, D51.2, D51.3, D51.8, D51.9), which may be considered medically necessary.

CODES*		
CPT	83918	Organic acids; total, quantitative, each specimen
	83919	Organic acids; qualitative, each specimen
	83921	Organic acid, single, quantitative
	81599	Unlisted multianalyte assay with algorithmic analysis

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Genova Diagnositcs. Organix® Comprehensive Profile https://www.gdx.net/product/organix-comprehensive-profile-metabolic-function-test-urine. Published 2024. Accessed 9/19/2024.
2. UpToDate. Organic acidemias: An overview and specific defects. https://www.uptodate.com/contents/organic-acidemias-an-overview-and-specific-defects. Published 2024. Accessed 9/19/2024.
3. UpToDate. Inborn errors of metabolism: Identifying the specific disorder. https://www.uptodate.com/contents/inborn-errors-of-metabolism-identifying-the-specific-disorder. Published 2024. Accessed 9/19/2024.
4. Gallagher RC, Pollard L, Scott AI, Huguenin S, Goodman S, Sun Q. Laboratory analysis of organic acids, 2018 update: a technical standard of the American College of Medical Genetics and Genomics (ACMG). *Genetics in Medicine.* 2018;20(7):683-691.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
11/2023	Annual review. No changes.
10/2024	Interim update. Update to diagnosis code configuration.
11/2024	Annual update. No changes to criteria or coding.
12/2025	Annual update. Add medically necessary criterion for methylmalonic acid testing for B12 deficiency. Update code configuration.