Medicare Medical Policy

Organic Acid Testing

MEDICARE MEDICAL POLICY NUMBER: 363

Effective Date: 11/1/2026

Last Review Date: 10/2026

Next Annual Review: 10/2027

MEDICARE COVERAGE CRITERIA 2
POLICY CROSS REFERENCES 3
POLICY GUIDELINES 3
REGULATORY STATUS 4
BILLING GUIDELINES AND CODING 4
REFERENCES 5
POLICY REVISION HISTORY 6

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines

Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*)

- **Medicare Coverage Manuals:** Medicare does not have criteria specific to organic acid testing in a coverage manual. **However, broad coverage requirements are provided by Medicare for diagnostic laboratory testing in general.** Specifically, Medicare requires diagnostic laboratory tests be ordered by a provider who is treating the member for a specific medical problem and who will promptly use the test results in the direct management of that specific medical problem.[1,2] These coverage criteria are considered "not fully established" under CFR § 422.101(6)(i)(A) as additional criteria are needed to interpret or supplement these general coverage provisions in order to determine medical necessity consistently.
- **National Coverage Determination (NCD):** While CMS has a portfolio of laboratory NCDs, they do not have an NCD for organic acid testing.
- **Local Coverage Determination (LCD)/Local Coverage Article (LCA):** According to Medicare guidelines, "Jurisdiction of payment requests for laboratory services furnished by an independent laboratory… lies with the A/B MAC (B) serving the area in which the laboratory test is performed."[3] As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for organic acid testing.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the service area in which the testing is being performed, Company criteria below are applied for medical necessity decision-making. Medicare statutes and regulation provide general coverage criteria for diagnostic testing, but additional criteria to interpret or supplement the Medicare criteria are being used in order to determine medical necessity consistently. These additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services **because the use of this additional criteria based on peer-reviewed evidence evaluates how testing is expected to improve health outcomes**. While organic acid testing is *newborns* is considered standard of care, there is minimal information or clinical studies on

	the validity and utility of organic acid testing to diagnose metabolic disorders in *adults*. Clinical practice guidelines do recommend the use of organic acid testing to diagnose metabolic disorders in adults, but organic acid testing is considered not medically necessary otherwise. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*
Organic Acid Testing	Company medical policy for Organic Acid Testing I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met. II. These services are considered **not medically necessary** for Medicare when the Company medical policy criteria are not met. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

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

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

Medicare requires diagnostic laboratory tests be ordered by a provider who is treating the member for a specific medical problem and who will use the test results in the direct management of that specific medical problem.[1,2] Thus, diagnostic testing must have established clinical utility and analytic validity.

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

In addition:

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Plan's Medicare policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

Since there are not fully established coverage criteria for organic acid testing available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the Medicare Coverage Criteria table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

Examples of panels which include multiple organic acids include but are not limited to the following:

- Metabolic Analysis Profile (Organic Acids) (Genova Diagnostics®)
- Organix® Basic Profile (Genova Diagnostics®)
- Organix® Comprehensive Profile (Genova Diagnostics®)
- Organix® Dysbiosis Profile (Genova Diagnostics®)
- Organic Acid Test (The Great Plains Laboratory, Inc.)

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

PROPER REPORTING OF LABORATORY PANEL TESTS

According to Company Coding Policy *(Laboratory Panel Billing,* 30.0*)*, when no specific CPT or HCPCS code exists for a panel test, the provider is required to report the panel service using an unlisted code. It is not appropriate for the provider to report 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 Centers for Medicare and Medicaid Services (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.

GENERAL

CPT codes for organic acids (83918, 83919, 83921) may be considered medically necessary 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 above CPT codes will deny as **not medically necessary.**

In addition to the above, CPT 83921 for methylmalonic acid (MMA) testing may also be used for potential B12 deficiency (D51.0, D51.1, D51.2, D51.3, D51.8, D51.9), which may be considered **medically necessary** as well.

CODES*		
CPT	81599	Unlisted multianalyte assay with algorithmic analysis
	83918	Organic acids; total, quantitative, each specimen
	83919	Organic acids; qualitative, each specimen
	83921	Organic acid, single, quantitative
HCPCS	None	

***Coding Notes:**

- The code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- 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. 42 CFR §410.32(a). https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec410-32.pdf. Accessed 8/19/2026.
2. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Accessed 8/19/2026.
3. CMS. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §50.5 - Jurisdiction of Laboratory Claims. Updated: 12/22/2014. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf. Accessed 8/19/2026.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	New Medicare Advantage medical policy (converted to new format 2/2023)
11/2023	Annual review, no change to criteria, but add Medicare references
10/2024	Interim update. Update to diagnosis code configuration.
11/2024	Annual review, no change to criteria
12/2025	Annual review, no change to criteria. Update to diagnosis code configuration to add B12 deficiency for methylmalonic acid (MMA) testing
11/2026	Annual review, no change to criteria