Medicare Medical Policy

Lidocaine Injections for Chronic Pain

MEDICARE MEDICAL POLICY NUMBER: 429

Effective Date: 4/1/2025	MEDICARE COVERAGE CRITERIA	. 2
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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").

X 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 <u>Policy Guidelines</u> below)

- Medicare Coverage Manuals: Medicare does not have criteria for the use of intravenous lidocaine injections for chronic pain in a coverage manual.
- National Coverage Determination (NCD): Medicare does not have an NCD for the use of lidocaine injections for chronic pain.
- Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA): As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for the use of lidocaine injections for chronic pain.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there are no fully established Medicare coverage criteria available.
- **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)].

Lidocaine Injections	Со	mpany medical policy for Lidocaine Injections for Chronic Pain
for Chronic Pain		
	١.	These services are considered not medically necessary for Medicare
		based on the Company medical policy. <u>See Policy Guidelines below.</u>

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)*

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POLICY CROSS REFERENCES

None

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

POLICY GUIDELINES

BACKGROUND

Lidocaine injections have been proposed for the management of chronic pain conditions. These injections, administered either locally at the site of pain <u>or</u> intravenously for systemic relief, are frequently utilized for neuropathic pain, musculoskeletal pain, and Complex Regional Pain Syndrome (CRPS).

DEFINITIONS

Lidocaine. A pharmacological agent that inhibits neural depolarization by acting on voltage-dependent sodium channels. It is extensively employed as a local anesthetic and is also administered systemically for the treatment of arrhythmias. The common adverse effects associated with lidocaine are generally mild to moderate, including general fatigue, somnolence, dizziness, headache, periorbital and extremity numbness and tingling, nausea, vomiting, tremors, and variations in blood pressure and pulse.

MEDICARE AND MEDICAL NECESSITY

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)

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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 the use of intravenous lidocaine injections for chronic pain available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the <u>Medicare Coverage Criteria</u> table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

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.

Intravenous lidocaine is approved by the U.S. Food and Drug Administration (FDA) for systemic use in the acute treatment of arrhythmias and for local anesthesia. However, **using IV lidocaine for the treatment of chronic pain or psychiatric disorders is considered an off-label use.**

BILLING GUIDELINES AND CODING

GENERAL

Intravenous lidocaine infusions may be generally considered **medically necessary** <u>unless</u> billed with any of the ICD-10 diagnosis codes listed in any of the Appendices below.

CODE	S*	
СРТ	96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
HCPCS	J2003	Injection, lidocaine hydrochloride, 1 mg

*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 <u>not</u> 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 <u>Medical Policy, Reimbursement Policy, Pharmacy</u> <u>Policy and Provider Information website</u> 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

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
4/2025	New Medicare Advantage medical policy

APPENDICES

Intravenous lidocaine infusions are considered **not medically necessary** when the codes for lidocaine (J2001) and infusion (96365) are billed together <u>AND</u> billed with one of the following diagnoses (ICD-10) codes.

Appendix I: Migraine

CODE	CODE	CODE	CODE
G43.00	G43.501	G43.809	G43.B0
G43.001	G43.509	G43.811	G43.B1
G43.009	G43.511	G43.819	G43.C0
G43.011	G43.519	G43.821	G43.C1
G43.019	G43.601	G43.829	G43.D0
G43.101	G43.609	G43.831	G43.D1
G43.109	G43.611	G43.839	G43.E0
G43.111	G43.619	G43.901	G43.E01
G43.119	G43.701	G43.909	G43.E09
G43.401	G43.709	G43.911	G43.E11
G43.409	G43.711	G43.919	G43.E19
G43.411	G43.719	G43.A0	
G43.419	G43.801	G43.A1	

Appendix II: Cluster Headaches

CODE	CODE	CODE	CODE
G44.001	G44.019	G44.039	G44.059
G44.009	G44.021	G44.041	G44.091
G44.01	G44.029	G44.049	G44.099
G44.011	G44.031	G44.051	

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Appendix III: Headaches

CODE	CODE	CODE	CODE
G44.1	G44.301	G44.41	G44.83
G44.201	G44.309	G44.51	G44.84
G44.209	G44.311	G44.52	G44.85
G44.211	G44.319	G44.53	G44.86
G44.219	G44.321	G44.59	G44.89
G44.221	G44.329	G44.81	R51.0
G44.229	G44.40	G44.82	R51.9

Appendix IV: Neuralgia, Neuropathy

CODE	CODE	CODE	CODE
B02.22	G90.519	G54.5	G61.82
B02.23	G90.521	G56.10	G62.89
B02.29	G90.522	G56.20	G62.9
G50.0	G90.523	G56.30	G63
G89.21	G90.529	G57.00	G90.0
G89.22	G90.59	G57.30	G90.01
G89.28	M79.7	G58.0	G90.09
G89.29	G62.0	G60.0	G90.9
G89.4	T45.1X5A	G60.1	G99.0
R39.82	T45.1X5D	G60.2	H46.2
G90.50	T45.1X5S	G60.3	H46.3
G90.51	M79.2	G60.8	H47.01
G90.511	R20.8	G60.9	H47.011
G90.512	R20.2	G61.1	H47.012
G90.513	G13.0	G61.81	H47.013

Appendix V: Diabetes (Neurological)

CODE	CODE	CODE	CODE	
E08.4	E10.4	E11.40	E13.40	
E09.4	E10.40	E11.41	E13.41	
E09.40	E10.41	E11.42	E13.42	
E09.41	E10.42	E11.43	E13.43	
E09.42	E10.43	E11.44	E13.44	
E09.43	E10.44	E11.49	E13.49	
E09.44	E10.49	E13.4		
E09.49	E11.4			