

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

Commercial (Small & Large Group) ASO Exchange/ACA
 Medicare Advantage (MAPD)

Intravenous Lidocaine for Chronic Pain

MB2301

Covered Service: NO

Prior Authorization Required: NO

Additional Information: Prescribed by (or in consultation with) pain specialists with prior authorization through The Plan Pharmacy Services.

Medicare Policy: Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

Wisconsin Medicaid Policy Coverage of prescription drug benefits is administered by the Wisconsin Medicaid program. Coverage of medical drug benefits is administered by the Wisconsin Medicaid fee-for-service program. Medical drugs not paid on a fee-for-service basis by the Wisconsin Medicaid program are covered by the plan with no PA required.

1.0 FDA Indication

1.1 Lidocaine

1.1.1 Intravenous lidocaine is approved by the U.S. Food and Drug Administration (FDA) for systemic use in the acute treatment of arrhythmias and locally as an anesthetic. IV lidocaine for the treatment of chronic pain is an off-label use.

1.2 Treatment Guidelines/Consensus statements:

1.2.1 American Society of Regional Anesthesia and Pain Medicine – Joint Consensus Guideline (2018) – IV Ketamine for Chronic Pain

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

- 1.2.1.1 Weak evidence supporting use of IV ketamine for short-term improvement in patients with spinal cord injury pain
- 1.2.1.2 Moderate evidence supporting use of IV ketamine for improvement in patients with complex regional pain syndrome (CRPS) up to 12 weeks
- 1.2.1.3 Weak or no evidence for immediate improvement for other pain conditions, including mixed neuropathic pain, fibromyalgia, cancer pain, ischemic pain, headache, and spinal pain.

2.0 Policy / Criteria:

- 2.1 IV Lidocaine is considered not covered due to insufficient evidence to demonstrate long-term clinical efficacy and safety for treatment of chronic pain
 - 2.1.1 Several randomized controlled trials (RCTs) have been performed using IV lidocaine for postherpetic neuralgia, CRPS, and diabetic neuropathy. These trials have failed to show a durable effect of lidocaine infusion on chronic pain.
 - 2.1.2 A 2005 Cochrane review examined controlled trials of lidocaine and its oral analogs (i.e., mexiletine, tocainide, flecainide) for neuropathic pain treatment and found the drugs safely provided more pain relief than placebo and with similar effectiveness as other analgesics. Reviewers noted that further investigation is needed to determine the clinical meaning of statistically significant pain relief and to test for less toxic analogs. A separate publication by the same authors estimated an 11-point (of 100) improvement in pain scales, with IV lidocaine or oral analogs compared with placebo. Although AEs were reported as not significantly different from other active controls (amitriptyline, carbamazepine, gabapentin, and morphine), the severity and nature of the AEs could not be assessed. As indicated in an accompanying editorial, “the limitations of the contributing studies preclude drawing useful conclusions about the adverse effect profiles of these drugs.” In addition, the authors noted that: 1) lidocaine’s short serum half-life (120 minutes) precludes its use for chronic pain and 2) all trials measured pain relief within 24 hours because, in most patients, the effect disappears a few hours after treatment. Given the high frequency of AEs and the short duration of action, the health benefits of IV lidocaine remain unclear for chronic pain.

3.0 Policy Rationale

- 3.1 The intense treatment protocols, the severity of adverse events, and the limited treatment durability raise questions about the net health benefit of IV lidocaine for chronic pain.
- 3.2 Additional clinical trials are needed to evaluate the long-term efficacy and safety of repeat courses of IV lidocaine for chronic pain.
- 3.3 The evidence is insufficient to determine that IV lidocaine results in an improvement in the net health outcome.

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

Comment(s):

1.0 *Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

1.1 NDC and HCPCS codes

| Medication Name | | How Supplied | National Drug Code (NDC) | HCPCS code |
|-----------------|-----------|--------------|--------------------------|------------|
| Brand | Generic | | | |
| Lidocaine | lidocaine | various | numerous | J2001 |

Committee/Source

Date(s)

| | |
|--|-------------------|
| Document Created: Medical Policy Committee/Health Services Division/Pharmacy Services | February 15, 2023 |
| Revised: Medical Policy Committee/Health Services Division/Pharmacy Services | |
| Reviewed: Medical Policy Committee/Health Services Division/Pharmacy Services | February 15, 2023 |
| Medical Policy Committee/Health Services Division/Pharmacy Services | August 21, 2024 |

Effective: 08/21/2024

Published: 08/21/2024

References:

1. Attal N, Gaude V, Brasseur L, et al. Intravenous lidocaine in central pain: a double-blind, placebo-controlled, psychophysical study. *Neurology*. Feb 8 2000; 54(3):564-574. PMID 10680784.
2. Baranowski AP, De Courcey J, Bonello E. A trial of intravenous lidocaine on the pain and allodynia of postherpetic neuralgia. *J Pain Symptom Manage*. Jun 1999; 17(6):429-433. PMID 10388248.
3. Kvarnstrom A, Karlsten R, Quiding H, et al. The effectiveness of intravenous ketamine and lidocaine on peripheral neuropathic pain. *Acta Anaesthesiol Scand*. Aug 2003; 47(7):868-877. PMID 12859309.
4. Medrik-Goldberg T, Lifschitz D, Pud D, et al. Intravenous lidocaine, amantadine, and placebo in the treatment of sciatica: a double-blind, randomized, controlled study. *Reg Anesth Pain Med*. Nov-Dec 1999; 24(6):534-540. PMID 10588558.

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

5. Sorensen J, Bengtsson A, Ahlner J, et al. Fibromyalgia--are there different mechanisms in the processing of pain? A double-blind crossover comparison of analgesic drugs. *J Rheumatol.* Aug 1997; 24(8):1615-1621. PMID9263160.
6. Wallace MS, Ridgeway BM, Leung AY, et al. Concentration-effect relationship of intravenous lidocaine on the allodynia of complex regional pain syndrome types I and II. *Anesthesiology.* Jan 2000; 92(1):75-83. PMID10638902.
7. Wu CL, Tella P, Staats PS, et al. Analgesic effects of intravenous lidocaine and morphine on postamputation pain: a randomized double-blind, active placebo-controlled, crossover trial. *Anesthesiology.* Apr 2002; 96(4):841-848. PMID 11964590.
8. Vlainich R, Issy AM, Sakata RK. Effect of intravenous lidocaine associated with amitriptyline on pain relief and plasma serotonin, norepinephrine, and dopamine concentrations in fibromyalgia. *Clin J Pain.* May 2011; 27(4):285-288. PMID 21178598.
9. Reutens DC, Fatovich DM, Stewart-Wynne EG, et al. Is intravenous lidocaine clinically effective in acute migraine? *Cephalalgia.* Dec 1991; 11(6):245-247. PMID 1790567.
10. Hand PJ, Stark RJ. Intravenous lignocaine infusions for severe chronic daily headache. *Med J Aust.* Feb 21 2000; 172(4):157-159. PMID 10772585.
11. Williams DR, Stark RJ. Intravenous lignocaine (lidocaine) infusion for the treatment of chronic daily headache with substantial medication overuse. *Cephalalgia.* Dec 2003; 23(10):963-971. PMID 14984229.
12. Tremont-Lukats IW, Hutson PR, Backonja MM. A randomized, double-masked, placebo-controlled pilot trial of extended IV lidocaine infusion for relief of ongoing neuropathic pain. *Clin J Pain.* Mar-Apr 2006; 22(3):266-271. PMID 16514327.
13. Carroll I, Gaeta R, Mackey S. Multivariate analysis of chronic pain patients undergoing lidocaine infusions: increasing pain severity and advancing age predict likelihood of clinically meaningful analgesia. *Clin J Pain.* Oct 2007; 23(8):702-706. PMID 17885349.
14. Challapalli V, Tremont-Lukats IW, McNicol ED, et al. Systemic administration of local anesthetic agents to relieve neuropathic pain. *Cochrane Database Syst Rev.* 2005(4):CD003345. PMID 16235318. Vyondys 53 Prescribing Information. Cambridge, MA: Sarepta Therapeutics, Inc.; December 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/211970s000lbl.pdf. Accessed January 2, 2020.
15. Tremont-Lukats IW, Challapalli V, McNicol ED, et al. Systemic administration of local anesthetics to relieve neuropathic pain: a systematic review and meta-analysis. *Anesth Analg.* Dec 2005; 101(6):1738-1749. PMID16301253.
16. Rathmell JP, Ballantyne JC. Local anesthetics for the treatment of neuropathic pain: on the limits of meta-analysis. *Anesth Analg.* Dec 2005; 101(6):1736-1737. PMID 16301252.
17. Przeklasa-Muszynska A, Kocot-Kepska M, Dobrogowski J, et al. Intravenous lidocaine infusions in a multidirectional model of treatment of neuropathic pain patients. *Pharmacol Rep.* Oct 2016; 68(5):1069-1075. PMID27552062
18. Finnerup NB, Biering-Sorensen F, Johannesen IL, et al. Intravenous lidocaine relieves spinal cord injury pain: a randomized controlled trial. *Anesthesiology.* May 2005; 102(5):1023-1030. PMID 15851891
19. Hocking G, Cousins MJ. Ketamine in chronic pain management: a evidence-based review. *Anesth Analg.* Dec 2003; 97(6):1730-1739. PMID14633551.

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

20. Motov S, Mai M, Pushkar I, et al. A prospective randomized, double-dummy trial comparing IV push low dose ketamine to short infusion of lowdose ketamine for treatment of pain in the ED. *Am J Emerg Med.* Aug 2017;35(8):1095-1100. PMID 28283340
21. Wertli MM, Kessels AG, Perez RS, et al. Rational pain management in complex regional pain syndrome 1 (CRPS 1)--a network meta-analysis. *PainMed.* Sep 2014; 15(9):1575-1589. PMID 25234478.
22. Schwartzman RJ, Alexander GM, Grothusen JR, et al. Outpatient intravenous ketamine for the treatment of complex regional pain syndrome: a double-blind placebo controlled study. *Pain.* Dec 15 2009; 147(1-3):107-115. PMID 19783371.
23. Sigtermans MJ, van Hilten JJ, Bauer MC, et al. Ketamine produces effective and long-term pain relief in patients with Complex Regional Pain Syndrome Type 1. *Pain.* Oct 2009; 145(3):304-311. PMID 19604642.
24. O'Connell NE, Wand BM, McAuley J, et al. Interventions for treating pain and disability in adults with complex regional pain syndrome. *Cochrane Database Syst Rev.* 2013; 4:CD009416. PMID 23633371.
25. Correll GE, Maleki J, Gracely EJ, et al. Subanesthetic ketamine infusion therapy: a retrospective analysis of a novel therapeutic approach to complex regional pain syndrome. *Pain Med.* Sep 2004; 5(3):263-275. PMID 15367304.
26. Kiefer RT, Rohr P, Ploppa A, et al. Efficacy of ketamine in anesthetic dosage for the treatment of refractory complex regional pain syndrome: an open-label phase II study. *Pain Med.* Nov 2008; 9(8):1173-1201. PMID 18266808.
27. Noppers IM, Niesters M, Aarts LP, et al. Drug-induced liver injury following a repeated course of ketamine treatment for chronic pain in CRPS type 1 patients: a report of 3 cases. *Pain.* Sep 2011; 152(9):2173-2178. PMID 21546160.
28. Noppers I, Niesters M, Swartjes M, et al. Absence of long-term analgesic effect from a short-term S-ketamine infusion on fibromyalgia pain: a randomized, prospective, double blind, active placebo-controlled trial. *Eur J Pain.* Oct 2011; 15(9):942-949. PMID 21482474.
29. Eichenberger U, Neff F, Svetcic G, et al. Chronic phantom limb pain: the effects of calcitonin, ketamine, and their combination on pain and sensory thresholds. *Anesth Analg.* Apr 2008; 106(4):1265-1273, table of contents. PMID 18349204.
30. Patil S, Anitescu M. Efficacy of outpatient ketamine infusions in refractory chronic pain syndromes: a 5-year retrospective analysis. *Pain Med.* Feb 2012; 13(2):263-269. PMID 21939497.
31. Webster LR, Walker MJ. Safety and efficacy of prolonged outpatient ketamine infusions for neuropathic pain. *Am J Ther.* Jul-Aug 2006; 13(4):300-305. PMID 16858163.
32. Kvarnstrom A, Karlsten R, Quiding H, et al. The analgesic effect of intravenous ketamine and lidocaine on pain after spinal cord injury. *Acta Anaesthesiol Scand.* Apr 2004; 8(4):498-506. PMID 15025615.
33. Amr YM. Multi-day low dose ketamine infusion as adjuvant to oral gabapentin in spinal cord injury related chronic pain: a prospective, randomized, double blind trial. *Pain Physician.* May-Jun 2010; 13(3):245-249. PMID 20495588.
34. American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Practice guidelines

Coverage of any drug intervention discussed in the plans prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and to applicable state and/or federal laws.

for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. *Anesthesiology*. Apr 2010; 112(4):810-833.
35. Intravenous Anesthetics for the Treatment of Chronic Pain. Chicago, Illinois: Blue Cross Blue Shield Association Medical Policy Reference Manual(2017 November) 5.01.16.