MEDICAL POLICY

POLICY TITLE	**OLINVYK (OLICERIDINE)**
POLICY NUMBER	**MP 2.385**

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**5/1/2024**

I. POLICY

Olinvyk (oliceridine) may be considered **medically necessary** when ALL of the following criteria are met:

- Member is greater than or equal to 18 years of age; AND
- Medication is being used for the management of acute severe pain and for whom alternative treatment options are inadequate; AND
- Treatment duration will not exceed 48 hours; AND
- Medication will only be given in non-residential inpatient or acute care outpatient facilities under clinical supervision.

All other uses of Olinvyk will be considered **not medically necessary.** There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

POLICY TITLE	OLINVYK (OLICERIDINE)
POLICY NUMBER	MP 2.385

III. DESCRIPTION/BACKGROUND

TOP

Oliceridine is a full opioid agonist and is relatively selective for the mu-opioid receptor. It is indicated in adults for the management of acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. Olinvyk has shown mild QTc interval prolongation with the maximum daily cumulative dose of 27 mg in a multiple-dose study. The cumulative total daily dose should not exceed 27 mg. Use of Olinvyk beyond 48 hours has not been studied in controlled clinical trials.

IV. RATIONALE

TOP

For individuals who have acute pain severe enough to require an intravenous opioid analgesic and for whom alternative treatments are inadequate. The evidence includes two phase 3 studies that evaluated the efficacy of Oliceridine in 790 adult patients with moderate to severe acute pain following orthopedic surgery-bunionectomy (APOLLO-1) and plastic surgery-abdominoplasty (APOLLO-2). Patients were randomized to receive Oliceridine 0.1mg, 0.35mg, or 0.5mg, placebo or morphine using patient-controlled analgesia. Findings from both studies showed a statistically greater analgesic effect in the Oliceridine 0.35mg and 0.5 mg treatment groups vs placebo over 48 hours. Additionally, an open-label, phase 3 study (ATHENA-1) found Oliceridine to be safe and well tolerated in a medically complex patient population, including elderly and obese patients, and those with comorbid conditions (i.e., diabetes, sleep apnea). The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

TOP

NA

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member’s health benefit plan for information or contact Capital Blue Cross for benefit information.

POLICY TITLE	OLINVYK (OLICERIDINE)
POLICY NUMBER	MP 2.385

VII. DISCLAIMER

TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement. The codes need to be in numerical order.

Covered when medically necessary:

Procedure Codes							
C9101	J3490						

ICD-10-CM Diagnosis Code	Description
G89.11	Acute pain due to trauma
G89.12	Acute post-thoracotomy pain
G89.18	Other acute postprocedural pain
G89.3	Neoplasm related pain (acute) (chronic)
R52	Pain, unspecified

IX. REFERENCES

TOP

1. *Olinvyk. Prescribing information. Trevena, Inc; 2021.*
2. *Park B. FDA Approves New IV Opioid Analgesic Olinvyk. Medical Professionals Reference.*

3. *Viscusi ER, Skobieranda F, Soergel DG, Cook E, Burt DA, Singla N. APOLLO-1: a randomized placebo and active-controlled phase III study investigating oliceridine (TRV130), a G protein-biased ligand at the micro-opioid receptor, for management of moderate-to-severe acute pain following bunionectomy. J Pain Res. 2019;12:927–943. doi: 10.2147/JPR.S171013*
4. *Singla NK, Skobieranda F, Soergel DG, et al. APOLLO-2: a randomized, placebo and active-controlled Phase III Study Investigating Oliceridine (TRV130), a G protein-biased ligand at the mu-opioid receptor, for management of moderate to severe acute pain following abdominoplasty. Pain Pract. 2019;19(7):715–731. doi: 10.1111/papr.12801*
5. *Bergese SD, Brzezinski M, Hammer GB, et al. ATHENA: a phase 3, open-label study of the safety and effectiveness of oliceridine (TRV130), A G-protein selective agonist at the micro-opioid receptor, in patients with moderate to severe acute pain requiring parenteral opioid therapy. J Pain Res. 2019;12:3113–3126. doi: 10.2147/JPR.S217563*

X. POLICY HISTORY

TOP

MP 2.385	**10/3/2022 Major review.** Creation of new policy.
	10/26/2023 Consensus review. References reviewed. No changes to coding.

Top