Medical Policy:

Xaracoll (bupivacaine hydrochloride) implant

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.334	January 2, 2025	February 2, 2021

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Bupivacaine blocks the generation and the conduction of nerve impulses, presumably by increasing the threshold for electrical excitation in the nerve, by slowing the propagation of the nerve impulse, and by reducing the rate of rise of the action potential.

Length of Authorization

- Approval will be granted for 7 days
- Subsequent approvals will require a new authorization

Dosing Limits [Medical Benefit]

The recommended dose of Xaracoll is 300 mg (3 x 100 mg implants) as a single administration. Xaracoll is intended for single-dose administration.

Guideline

I. INITIAL APPROVAL CRITERIA

1. **Postsurgical Analgesia**
   Coverage is provided in the following condition:
   A. Patient is 18 years of age and older; **AND**
   B. Xaracoll will be used for postsurgical analgesia for up to 24 hours following open inguinal hernia repair

Limitations/Exclusions

1. Xaracoll is considered investigational and not medically necessary for any indications other than the one listed above.
2. Xaracoll is contraindicated in obstetrical paracervical block anesthesia

Applicable Procedure Codes

Code	Description
C9089	Xaracoll 100mg implant , bupivacaine, collagen-matrix implant, 1 mg
J3490	Xaracoll 100mg implant, unclassified drugs

Applicable NDCs

Code	Description
51715-0100-04	Xaracoll 3x100mg Implant
51715-0100-10	Xaracoll 3x100mg Implant
51715-0100-03	Xaracoll 100mg

ICD-10 Diagnoses

Code	Description
K40.91	Unilateral inguinal hernia, without obstruction, without gangrene, recurrent
K40	Inguinal hernia

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	3/14/2023	Annual Review: no revisions
EmblemHealth & ConnectiCare	1/18/2023	Transfer to New Template, removed code C9399, added C9089

EmblemHealth & ConnectiCare	2/2/2021	New Policy

References

1. Xaracoll Prescribing Information. Athlone, Ireland: Innocoll Pharmaceuticals Limited; 2020