

<b>Policy Name:</b>	<b>Intravascular Shockwave Lithotripsy for Treatment of Coronary Artery Disease</b>
<b>Effective Date:</b>	<b>7/17/2023</b>

## Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

## Coverage Policy

Intravascular shockwave lithotripsy for treatment of coronary artery disease is considered investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

## Description

The Shockwave Coronary Intravascular Lithotripsy (IVL) is intended for endovascular interventions to treat severely calcified de novo coronary lesions in patients with coronary artery disease (CAD). The system uses lithotripsy combined with angioplasty to generate sonic pressure waves in a balloon-based system.

Coronary intravascular lithotripsy (IVL) has been proposed for vessel preparation in the presence of coronary artery calcification prior to stent delivery. IVL is a novel technique based on an established treatment strategy for renal calculi, in which multiple lithotripsy emitters mounted on a traditional catheter platform deliver localized pulsatile sonic pressure waves to circumferentially modify vascular calcium. The waves induce fracture in the calcium deposits to widen the vessel lumen and stent expansion to treat severely calcified coronary lesions. In contrast to ultrasound technologies, which are characterized by low amplitude but very high frequency waveforms, an acoustic pressure shockwave has a very high amplitude but low frequency.

The Shockwave Intravascular Lithotripsy (IVL) System consists of the Shockwave C2 Coronary IVL Catheter, the IVL Generator, the IVL Connector Cable, and its accessories.

## FDA Approval

February 2021, the FDA granted premarket approval (PMA) for Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (Shockwave Medical, Inc., Santa Clara, CA). The device is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.

## Medica Coverage Policy



### **Prior Authorization**

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

### **Coding Considerations**

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

### **CPT Codes**

Original Effective Date: 7/17/2023

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