NO. 91639

INTRAVASCULAR LITHOTRIPSY

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This medical policy addresses the use of intravascular lithotripsy in both the arteries of the lower extremities and the coronary arteries.

I. MEDICAL NECESSITY CRITERIA

A. Intravascular lithotripsy for endovascular revascularization of the lower extremities is medically necessary when the following criteria are met:

1. Target lesion is located in a native, de novo artery
2. Target lesion is ≥ 70% stenosis by visual estimate:
    a. 70 to 99% stenosed: Target lesion length ≤ 180 mm
    b. Chronic total occlusion: Lesion length ≥ 20 mm
3. Member has at least one patent tibial vessel on the target leg with runoff to the foot (defined as no stenosis > 50%)
4. Calcified lesion

B. Intravascular lithotripsy for endovascular revascularization of the lower extremities is not medically necessary if any the following are present:

1. Target lesion is below the knee.
2. In-stent restenosis within 10 mm of the target zone.
3. Lesions within 10 mm of the ostium of the SFA or within 10 mm of the ostium of the anterior tibial artery.
4. Evidence of aneurysm or thrombus in target vessel.
5. No calcium in the target lesion.
6. Target lesion within native or synthetic vessel grafts.

7. Failure to successfully cross the guidewire across the target lesion (successful crossing defined as tip of the guidewire distal to the target lesion in the absence of flow limiting dissections or perforations)

C. Intravascular lithotripsy for endovascular revascularization of the coronary arteries is experimental and investigational due to insufficient evidence of effectiveness in improving clinical outcomes.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
Wellpoint federal (formerly National Government Services, Inc.)	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

Intravascular lithotripsy (IVL) is a technique that evolved from the established therapy for renal and ureteral calculi. IVL combines ultrasound mechanical pulse waves with angioplasty to purportedly treat calcified plaque in stenotic or occluded peripheral arteries. The system consists of a single-use proprietary balloon catheter, a reusable generator, and a reusable connector cable. The balloon catheter has integrated lithotripsy emitters designed to enhance angioplasty by disrupting calcified lesions before balloon revascularization.

Peripheral lithotripsy

The **U.S. Food and Drug Administration (FDA)** granted the Shockwave Medical **Intravascular Lithotripsy (IVL)** System (Shockwave Medical, Inc., Fremont, CA) initial Class II device 510(k) Premarket Notification (K180454) on June 27, 2018. The device is classified as a *Percutaneous Catheter, Ultrasound (Intended for ultrasound wave enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature)*, Product Code PPN. **Indications for use**: *The Shockwave Medical Intravascular Lithotripsy (IVL) System is intended for lithotripsy-enhanced balloon dilatation of lesions, including calcified lesions, in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries. Not for use in the coronary or cerebral vasculature*.

The following are generally applicable to intravascular lithotripsy:

- Used for severe calcified lesions where a balloon crosses but does not fully dilate
- Used as an adjunct to atherectomy therapy for infrequent but difficult cases
- Average hospital utilization is generally between 2 and 8% of percutaneous coronary interventions

Currently, the Disrupt BTK trial (Shockwave Medical Peripheral Lithoplasty System Study for Below The Knee Peripheral Artery Disease) represents the largest high quality trial evaluating the safety and feasibility of performing intravascular lithotripsy for calcified lesions in the arteries below the knee. The design was prospective and nonrandomized trial conducted in Germany, Austria, and New Zealand. The study had a safety endpoint of a composite of major events including emergent surgical intervention for revascularization or amputation, myocardial infarction, or death which at the end of the study was 0%. The effectiveness endpoint for this study based on reduction of the target lesion which was further defined as a secondary endpoint of procedural success if there was ≤50% diameter of the residual stenosis after IVL therapy. Both endpoints were achieved in all patients that were successfully treated with IVL. However, this has been the only study to date and had a limited cohort of patients. There is a sequel trial named Disrupt BTK II. The study design is a single-arm, multicenter, prospective study that will be including patients with critical limb ischemia anywhere from the distal segment of the popliteal artery all the way down to the ankle joint. Moreover, the study included patients with up to 2 target lesions in native arteries that have a vessel diameter of 2–4 mm and a length of ≤200 mm. The study is expected to be completed by the end of 2023.

In a 2026 systematic review by Kofiah and colleagues including 14 studies, the outcomes of IVL for calcified femoropopliteal and infrapopliteal lesions were analyzed. IVL consistently demonstrated high procedural success (>95%), low rates of major dissection (≤5.5%), minimal perforation (≤1.1%), and a reduced need for bailout stenting compared to conventional angioplasty. Compared to atherectomy, IVL showed a superior safety profile with lower rates of perforation and distal embolization. Relative to high-pressure balloons, IVL achieved similar luminal gain with significantly fewer flow-limiting dissections.

Coronary lithotripsy

Shockwave Medical Inc. received FDA Pre-Market Approval for the Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary IVL Catheter on February 12, 2021 (P200039). This product is regulated as a class III device and is

assigned product code QMG (shockwave intravascular lithotripsy system). *The Shockwave C2 Coronary IVL Catheter system is intended "for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting.*

In the DISRUPT CAD III trial, 431 subjects were enrolled across 47 sites internationally in a prospective, single-arm study design. The primary safety endpoint of the 30-day freedom from major adverse cardiovascular events was 92.2%; the lower bound of the 95% confidence interval was 89.9%, which exceeded the pre-specified performance goal of 84.4% ($p < 0.0001$). The primary effectiveness endpoint of procedural success was 92.4%; the lower bound of the 95% confidence interval was 90.2%, which exceeded the performance goal of 83.4% ($p < 0.0001$). Mean calcified segment length was 47.9 ± 18.8 mm, calcium angle was 292.5 ± 76.5°, and calcium thickness was 0.96 ± 0.25 mm at the site of maximum calcification. OCT demonstrated multiplane and longitudinal calcium fractures after IVL in 67.4% of lesions. Minimum stent area was 6.5 ± 2.1 mm2 and was similar regardless of demonstrable fractures on OCT. (Hill et al., 2020)

The BENELUX-IVL registry enrolled patients in 9 hospitals across 4 countries who underwent percutaneous coronary intervention (PCI) with IVL and retrospectively stratified them into two groups: advanced age (≥80 years) and younger (<80 years). The primary technical endpoint was technical success, defined as successful IVL catheter crossing of the target lesion with residual stenosis <30%. The primary safety endpoint was in-hospital major adverse cardiac events (MACE). Between January 2019 and April 2025, 583 patients underwent PCI with IVL; of these, 147 (25.2%) patients were aged ≥80 years (advanced age cohort), and the remaining 436 (74.8%) were aged <80 years (younger cohort). Compared to younger patients, the advanced age cohort had higher SYNTAX score (23 [IQR 15-32] vs. 18 [IQR 11-28], $p = 0.01$) and more comorbidities. Intraprocedural complications (severe dissection, abrupt vessel closure, and perforation) were low in both groups, with no significant differences between them. Technical success was comparable between the advanced age and younger populations (87.8% vs. 90.6%, RR: 0.97 (0.91-1.04), $p = 0.32$). In-hospital MACE rates were similar between the advanced age and younger cohorts (1.4% vs. 2.1%, RR: 0.64 (0.19-2.18), $p = 0.59$), and these results remained consistent at 1-year follow-up (6.1% vs. 8.0%, RR: 0.76 (0.38-1.55) $p = 0.51$). (Oliveri et al., 2025)

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
Society for Cardiovascular Angiography and Interventions (SCAI)	SCAI Expert Consensus Statement on the Management of Calcified Coronary Lesions (2024)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date
Shockwave Medical Intravascular Lithotripsy (IVL) System	K180454	6/27/2018
Shockwave C2 Coronary IVL Catheter / Shockwave Intravascular Lithotripsy (IVL) System	P200039	2/12/2021

VI. CODING

See also *Priority Health Medical Policy No. 91636 - Category III Current Procedural Terminology (CPT®) Codes ("T" codes)*

Lower extremity artery(ies) EXCEPT tibial/peroneal

C9764 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed

C9765 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed

C9766 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed

C9767 Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

37262 Intravascular lithotripsy(ies), iliac vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)

37279 Intravascular lithotripsy(ies), femoral and popliteal vascular territory, including all imaging guidance and radiological supervision and interpretation necessary to perform the intravascular lithotripsy(ies) within the same artery (List separately in addition to code for primary procedure)

Tibial/peroneal artery (ies) *Not payable for commercial products*

C9772 Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed

C9773 Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed

C9774 Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed

C9775 Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed

Coronary artery(ies):
Not Medically Necessary
C1761 Catheter, transluminal intravascular lithotripsy, coronary

92972 Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access Evicore guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access InterQual guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access EviCore, InterQual, or TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a

chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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SUMMARY OF CHANGES

- Formatting, updated background and references

Past committee review dates: 8/23, 8/24, 8/25, 8/26

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The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.