Priority Health

MEDICAL POLICY
No. 91639-R0

INTRAVASCULAR LITHOTRIPSY

Effective Date: October 23, 2023	**Review Dates: 8/23**
Date Of Origin: August 23, 2023	**Status: New**

I. POLICY/CRITERIA

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

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. MEDICAL NECESSITY REVIEW

☐ Required ☒ Not Required ☐ Not Applicable

III. APPLICATION TO PRODUCTS

Coverage is subject to 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, 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.***

IV. 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) is the only study available that investigated the safety and feasibility of performing intravascular lithotripsy for calcified lesions in the arteries below the knee.15 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.

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*.

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

In 2021 Hayes, Inc. concluded that available clinical studies and systematic reviews demonstrated minimal support for using Shockwave IVL System with C2 Coronary IVL catheter for treatment of calcified coronary lesions, while available clinical practice guidelines confer weak support.

> *Findings from studies indicate that intravascular lithotripsy (IVL) for coronary artery disease (CAD) is technically feasible and associated with improved diameter stenosis with minimal complications. However, current evidence does not inform whether using IVL before other catheter-based interventions (e.g., stents, balloon therapy) improves long-term clinical outcomes, due to a lack of comparison groups and short duration of study follow-up. Further, because patients often received both IVL and other catheter-based interventions, the influence of IVL cannot be isolated and may be confounded by the effects of the other interventions.*

V. CODING INFORMATION

Lower extremity artery(ies) EXCEPT tibial/peroneal *(Covered for Commercial, Medicare, Medicaid)*

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

Tibial/peroneal artery (ies) *(Covered for Medicare. Not Separately Payable for Commercial and Medicaid.)*

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):
C1761 Catheter, transluminal intravascular lithotripsy, coronary *(Covered for Medicare only)*
0715T Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure) *(Not separately payable- Commercial, Medicare, and Medicaid)*

VI. REFERENCES

Intravascular lithotripsy for coronary and peripheral applications was reviewed by the Priority Health **Technology Assessment Committee (TAC)** on June 21, 2023.

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