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Medicare Advantage Policy Manual **Policy ID:** M-SUR 233

Coronary Intravascular Lithotripsy

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Coronary intravascular lithotripsy is used to prepare stenotic, calcified de novo coronary vessels for stent placement. Ultrasound waves are applied intravascularly to selectively break-up calcium deposits to aid with stent placement.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy only applies to coronary intravascular lithotripsy.

CMS Coverage Manuals*	None

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available for Coronary Intravascular Lithotripsy. Therefore, the health plan's medical policy is applicable.* Coronary Intravascular Lithotripsy, Surgery, Policy No. 233 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

In 2021, The US Food and Drug administration (FDA) granted Premarket Approval (PMA) for the Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (Product code QMG, PMA number P200039). (1)

The Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic *de novo* coronary arteries prior to stenting.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

None

REFERENCES

1. FDA (FDA). FDA. Food and Drug Administration; Premarket Approval - Shockwave Intravascular Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter (P200039). [cited 12/18/2024]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200039A.pdf .

CODING

Codes	Number	Description
CPT	92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)
HCPCS	C1761	Catheter, transluminal intravascular lithotripsy, coronary

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*