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Medicare Advantage Policy Manual **Policy ID:** M-DME98

Mechanical Residual Limb Volume Management System for Upper Extremity Prostheses

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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

The RevoFit® system is a mechanical limb volume adjustment system designed for prosthetic sockets. The system allows users to make more convenient volume adjustments than with standard strap and padding systems. The system is designed to address daily residual limb volume fluctuations, changes in prosthetic fit and control, and user comfort.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None
Medical Policy Manual	*Medicare coverage guidance is not available for mechanical limb volume adjustment systems (e.g., RevoFit®) for use with upper extremity prostheses. Therefore, the health plan's medical policy is applicable.* Mechanical Residual Limb Volume Management System for Upper Extremity Prostheses, Durable Medical Equipment, Policy No. 98

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below must be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Product information (manufacturer name, model number)
- Physician's order (if applicable)

REGULATORY STATUS

Many prosthetic devices are classified as Class I medical devices by the United States Food and Drug Administration (FDA) and are therefore exempt from premarket notification requirements. Certain specialized prosthetic devices may be classified as Class II medical devices and require premarket approval. While many prosthetic devices do not require FDA premarket approval, devices must still comply with applicable FDA regulations and quality standards. The RevoFit® system is classified as a Class I medical device and does require FDA premarket approval.

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

1. Durable Medical Equipment, Prosthetic and Orthotic Replacements, Duplicates, Repairs, and Upgrades to Existing Equipment, Durable Medical Equipment, Policy No. M-75
2. Myoelectric Prosthetic and Orthotic Components for the Upper Limb, Durable Medical Equipment, Policy No. M-80
3. General Medical Necessity Guidance for Durable Medical Equipment, Prosthetic, Orthotics and Supplies (DMEPOS), Durable Medical Equipment, Policy No. M-88

REFERENCES

None

CODING

Codes	Number	Description
CPT	None	
HCPCS	L7406	Addition to upper extremity, user adjustable, mechanical, residual limb volume management system

***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.*