Regence

Medical Policy Manual Durable Medical Equipment, Policy No. 98

Mechanical Residual Limb Volume Management System for Upper Extremity Prostheses

Effective: April 1, 2025

Next Review: March 2026
Last Review: March 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

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.

MEDICAL POLICY CRITERIA

Notes: This policy applies to the codes listed in the policy criteria as noted. Unlisted codes should not be used if there is a specific code that is applicable.

Use of a mechanical reel-based socket volume adjustment system with an upper extremity prosthesis, including but not limited to the RevoFit® system, is considered **not medically necessary.**

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

LIST OF INFORMATION NEEDED FOR REVIEW

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)

CROSS REFERENCES

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

BACKGROUND

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.

REVOFIT®

The RevoFit® system is a reel-based adjustable prosthetic socket technology designed to provide residual limb volume management for prosthetic users. RevoFit® uses a click reel consisting of an adjustable dial, strong light-weight laces and lace guides. The dial uses a gearing mechanism that advances the lace and moveable portions. This click reel and lacing system adjust to pre-determined areas of the socket customized to the prosthetic user. The system is designed to control compression and expansion to manage fluctuation of residual limb volume to ease donning and doffing and provide more convenient volume adjustments than standard strap and padding systems.

EVIDENCE SUMMARY

Systematic Reviews

Baldock (2023) published a systematic review of adjustable prosthetic sockets, analyzing both research literature and patents of commercial designs.[1] The review identified 50 research articles which assessed 63 patients total and 35 different socket designs, including RevoFit®. Types of adjustable sockets identified included inflatable bladders, moveable panels, circumferential adjustment, and variable length. Included studies were small case or cohort studies (median=10 participants), and most did not study a commercially available socket.

Most studies reported improved patient comfort with an adjustable socket, but most improvements were not statistically significant. The reviewers identified two case studies which assessed use of RevoFit® among transtibial amputees, but neither study included a comparator or analysis of clinical outcomes. Overall, the included studies had several limitations including small sample size, lack of long-term testing, and lack of prospective study design. The reviewers also noted that 68% of commercially available adjustable sockets lack published research, and most adjustable sockets lack appropriate safety features to limit over- or under-tightening which can cause tissue damage.

Section Summary

Evidence for reel-based adjustable prosthetic sockets includes one systematic review and small case and cohort studies, most of which did not include control groups. The evidence is insufficient to conclude that adjustable prosthetic sockets improve health outcomes for individuals with upper extremity prostheses. Evidence for RevoFit® includes cases studies of transtibial amputees which did not analyze clinical outcomes. No peer-reviewed published studies have assessed RevoFit® with upper extremity prostheses. Additional, well-designed, comparative studies are necessary to evaluate the safety and effectiveness of reel-based adjustable prosthetic sockets.

PRACTICE GUIDELINE SUMMARY

No clinical practice guidelines addressing reel-based adjustable prosthetic sockets were identified.

SUMMARY

There is not enough research to show that reel-based adjustable prosthetic sockets improve health outcomes for people with upper extremity prostheses when compared with traditional socket adjustments. No published studies have evaluated the use of reel-based adjustable prosthetic sockets (e.g., RevoFit®) for use with upper extremity prostheses. In addition, no clinical practice guidelines were identified which recommend reel-based adjustable prosthetic sockets. Therefore, reel-based adjustable prosthetic sockets are considered not medically necessary.

REFERENCES

1. Baldock M, Pickard N, Prince M, et al. Adjustable prosthetic sockets: a systematic review of industrial and research design characteristics and their justifications. *J Neuroeng Rehabil.* 2023;20(1):147. PMID: 37926807

CODES

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

Date of Origin: *March 2025*