ProHensor® Reimbursement Guide

Reference Guide

Last Updated: August 1, 2025

Disclaimer - General Nature of Reimbursement Guide

This Reimbursement Guide (Guide) is intended to provide general information to assist you in invoicing and receiving payment from third-party payers for the provision of the applicable orthotic or prosthetic (O&P) device or component (the Product) you purchase from Marins Inc. and provide to your patient. However, you as a certified O&P clinician, O&P patient care facility [or DME provider], as applicable (the Provider), are fully responsible for accurately billing for the Product, as well as for establishing medical necessity, confirming payer coverage criteria are met, and use appropriate HCPCS codes, modifiers and charges for the applicable Product and related services.

The information contained in this Guide is for general information only, and MARINS INC. assumes no responsibility for errors or omissions contained in this Guide, which is made available without charge or cost to our customers who purchase the Product. The information and advice contained in this Guide is provided on an "as is" basis with no representations, warranties or guaranties regarding completeness, accuracy or effectiveness.

Your use of the information and advice contained in this Guide is at your sole choice and risk. You should not rely on the provided information or advice as a substitute for, nor does it replace, your own informed judgment and responsibility. Suggested HCPCS coding is provided for reference only. It is your responsibility as the Provider submitting the claim to determine and submit correct coding that conforms with all the established rules and regulations of the applicable payer. We recommend that you contact the applicable payer for coding and coverage guidance prior to delivering the Product to your patient and submitting the related claim. This Guide is based upon what we believe is reasonable judgment regarding coverage and claim submission, but it does not replace your responsibility in that regard as the Provider of the Product to your patient.

The Product information included in this Guide is intended for general information purposes only. It is not intended as advice with respect to the appropriateness of the use of the Product for any patient.

Your use of this Guide and the information it contains, including implementation or use of any suggestion or advice included in this Guide, does not create a professional-client relationship between MARINS INC. or any of its affiliates and you, and the content of this Guide is not intended to be and should not be considered legal or professional revenue cycle management advice.

MARINS INC. may, but undertakes no responsibility to, update this Guide from time to time.

PROHENSOR® REIMBURSEMENT GUIDE

Disclaimer - General Nature of Reimbursement Guide

TABLE OF CONTENTS

Introduction

PART 1: ProHensor® VC (L6722)

PART 2: VCAL Cartridge (L7499)

PART 3: Combined System (VC + VCAL)

PART 4: General Information

Appendices

QUICK REFERENCE SUMMARY SHEET

(For Billing & Reimbursement Use Only)

HOW TO USE THIS GUIDE

PART 1: PROHENSOR® VC (L6722)

Device Overview

User Profile: ProHensor® VC

HCPCS Coding for ProHensor® VC

Billing Guidelines: ProHensor® VC

If Billing Is Denied: ProHensor® VC

Sample Letter of Medical Necessity: ProHensor® VC

PART 2: VCAL CARTRIDGE (L7499)

Component Overview

Clinical Benefits & Medical Necessity

Medical Necessity: Who Benefits from VCAL

HCPCS Coding for VCAL Cartridge

Why PDAC Is Not Required for VCAL

Billing Guidelines: VCAL Cartridge

If Billing Is Denied: VCAL Cartridge

Sample Letter of Medical Necessity: VCAL Cartridge

PART 3: COMBINED SYSTEM (VC + VCAL)

Clinical Rationale for Prescribing Both Together

Billing Strategy for Combined Purchase

Sample Letter of Medical Necessity: Combined System

Activities Where the Complete System Excels

PART 4: GENERAL INFORMATION

Billing Code Context

FDA Status

ProHensor® Limited Warranty

Service & Maintenance Information

APPENDICES

Appendix A: Coding Descriptors

Appendix B: Visual Comparison Tables

Appendix C: Functional Activities Table

Appendix D: Appeal Letter Templates

CONTACT INFORMATION

Quick Reference Summary Sheet

(For Billing & Reimbursement Use Only)

ProHensor® VC (Voluntary Closing)

Device Description
The ProHensor® VC is a body-powered, voluntary-closing terminal device designed for upper-limb amputees at or above the wrist. It provides proprioceptive feedback through cable tension, enabling intuitive grip force modulation. Built for durability and heavy-duty use, the ProHensor VC is field-serviceable and compatible with standard body-powered harness systems.

Suggested HCPCS Code
L6722 – Terminal Device, Hook or Hand, Heavy Duty, Mechanical, Voluntary Closing, Any Material, Any Size, Lined or Unlined

Why L6722 Applies

- Heavy-duty voluntary-closing terminal device
- Proprioceptive feedback for grip force control
- Durable for industrial, trade, and occupational use
- Compatible with standard prosthetic systems
- Field-serviceable for long-term reliability

PDAC Status
Marins Inc. will pursue PDAC verification for ProHensor VC under **L6722** once FDA establishment registration is complete. Contact Marins Inc. for current status: Admin@MarinsMed.com

---

VCAL Cartridge (Voluntary Closing with Auto-Locking)

Component Description
The VCAL (Voluntary Closing with Auto-Locking) Cartridge is a proprietary, field-replaceable component compatible with all ProSeries terminal devices. When installed in a ProHensor VC, it adds an integrated auto-locking mechanism that maintains grip without continuous cable tension.

Suggested HCPCS Code
L7499 – Upper Extremity Prosthesis, Not Otherwise Specified

Why L7499 is Appropriate

- No existing HCPCS code describes voluntary-closing devices with integrated auto-locking capability
- Adds functionality beyond **L6722** predicate device
- Provides unique locking mechanism with three operational modes
- Not PDAC-reviewed as an **L6722** component

Key Clinical Benefits

- Enhances safety by maintaining secure grip
- Prevents overuse injuries and reduces fatigue

- Reduces cognitive load during tasks
- Expands functional working envelope
- Three operational modes: Wide Grip, Narrow Grip, VC-Only Mode

PDAC Status
PDAC verification not required for **L7499** (miscellaneous/non-specified code). Comprehensive documentation of medical necessity is essential for reimbursement.

Billing Tip

For ProHensor VC (L6722):

- Use standard documentation for heavy-duty VC devices
- Verify PDAC status with Marins Inc. before submitting Medicare claims
- Include clinical justification for heavy-duty rating

For VCAL Cartridge (L7499):

- Always attach detailed narrative letter explaining auto-locking mechanism
- Include physician prescription with locking capability language
- Document occupational demands requiring sustained grip
- Emphasize clinical benefits: safety, fatigue prevention, cognitive load reduction, working envelope expansion
- If denied, use appeal letter template with supporting documentation

Clinical Recommendation:
For optimal patient outcomes, prescribe ProHensor VC + VCAL Cartridge together when patient has occupational demands, sustained grip requirements, or risk factors for prosthetic abandonment.

How to Use This Guide

This guide is structured to provide clear, comprehensive information for billing the ProHensor® system components.

If you are prescribing ProHensor VC only:

- Review PART 1 for complete **L6722** billing information
- Use ProHensor VC sample letter template

If you are prescribing VCAL Cartridge only (as upgrade to existing ProHensor VC):

- Review PART 2 for complete **L7499** billing information
- Use VCAL Cartridge sample letter template

If you are prescribing both ProHensor VC and VCAL Cartridge together:

- Review PART 1, PART 2, and PART 3
- Use combined system sample letter template

- Bill as separate line items with individual justifications

For general reference:

- PART 4 provides context, FDA status, and warranty information
- Appendices include coding descriptors, comparison tables, and appeal templates

Contact Information:
For questions about products, PDAC status, or reimbursement support:
Marins Inc. | Admin@MarinsMed.com

PART 1: ProHensor® VC (L6722)

Device Overview

The ProHensor® VC is a body-powered, voluntary-closing terminal device designed for upper-limb amputees with amputation at the wrist or higher. Built for strength, durability, and precision, the ProHensor VC delivers reliable performance in demanding environments.

Design Features

Voluntary-Closing Mechanism
The ProHensor VC uses cable-actuated voluntary closing, allowing users to control grip force through harness tension. This provides intuitive, proportional control with real-time proprioceptive feedback.

Heavy-Duty Construction
Engineered for industrial, trade, and occupational use, the ProHensor VC withstands:

- Harsh environments (dirt, sawdust, moisture)
- Vibration from power tools and machinery
- Medium to heavy-duty activities of daily living
- Repetitive use in demanding conditions

Field-Serviceable Design
Modular construction allows prosthetists or informed users to perform routine maintenance and repairs, minimizing downtime and extending device lifespan.

Standard Compatibility
Integrates seamlessly with:

- Standard body-powered harness systems
- Common wrist units and quick-disconnect systems
- Existing prosthetic setups without requiring system overhaul

Key Advantages

Feature	Benefit
Proprioceptive Feedback	Users feel grip force through cable tension, enabling intuitive control
Mechanical Reliability	No batteries, electronics, or software to fail
Environmental Durability	Maintains function in rain, dust, and harsh conditions
Close-to-Body Gripping	Increases functional working envelope and improves ergonomics
Quick Maintenance	Field-serviceable design reduces repair time and costs

---

User Profile: ProHensor® VC

Who Benefits from ProHensor VC

Ideal candidates include:

- Individuals requiring reliable, durable body-powered prosthetics
- Users who value proprioceptive feedback for grip control
- Those working in industrial, trade, and hands-on professions
- Amputees seeking field-serviceable devices to minimize downtime
- Users who want to complement myoelectric devices with mechanical backup
- Individuals with active lifestyles requiring medium to heavy-duty capability

Activities Where ProHensor VC Excels

Heavy-Duty Work & Daily Activities

- Trades and labor: Construction, mechanical work, plumbing, electrical tasks
- Hand and power tools: Wrenches, drills, hammer drills, reciprocating saws
- Yard and maintenance: Shoveling, raking, lifting, using motorized landscaping tools

Tasks Involving Vibration & Harsh Environments

- Outdoor and industrial work: Working in rain, exposure to dirt and sawdust
- Machinery operation: Sanders, impact wrenches, pneumatic tools

Dynamic Grip Tasks

- Variable force application requiring constant adjustment
- Repetitive gripping and releasing operations
- Tasks requiring fine motor control and delicate object handling

Clinical Considerations

ProHensor VC is appropriate when:

- Patient performs varied, dynamic grip tasks
- Proprioceptive feedback is clinically valuable

- Heavy-duty mechanical device is medically necessary
- Budget considerations exist at initial fitting (with option to add VCAL later)

Consider adding VCAL Cartridge when:

- Patient performs sustained grip tasks causing fatigue
- Occupational demands require hands-free hold capability
- Risk factors for overuse injuries or prosthetic abandonment exist
- Maximum functional capability and safety are clinical priorities

---

HCPCS Coding for ProHensor® VC

Suggested Code: L6722

L6722: TERMINAL DEVICE, HOOK OR HAND, HEAVY DUTY, MECHANICAL, VOLUNTARY CLOSING, ANY MATERIAL, ANY SIZE, LINED OR UNLINED.

Code Justification

The ProHensor VC meets all criteria for **L6722**:

Heavy Duty:
Designed for industrial and occupational use, rated for medium to heavy activities of daily living, withstands harsh environments and sustained use.

Mechanical:
Body-powered operation through cable and harness system, no electronic or powered components.

Voluntary Closing:
User controls grip force through cable tension, providing proportional force modulation with proprioceptive feedback.

Material and Construction:
Durable materials suitable for demanding applications, field-serviceable design for long-term reliability.

PDAC Requirements

Medicare Coverage:
PDAC verification is required for Medicare reimbursement under **L6722**. Marins Inc. will pursue PDAC verification once FDA establishment registration is complete.

Current Status:
Contact Marins Inc. at Admin@MarinsMed.com for the most current PDAC verification status before submitting Medicare claims.

Commercial Payers:
Many commercial insurance plans follow Medicare guidelines and may also require PDAC verification for **L6722** devices. Contact specific payers for their requirements.

Billing Guidelines: ProHensor® VC

Documentation Requirements

Required Documentation for L6722:

Prescription from Physician

- Terminal device prescription specifying heavy-duty voluntary closing
- Patient diagnosis and amputation level
- Medical necessity for prosthetic intervention

Letter of Medical Necessity from Prosthetist

- Clinical evaluation and functional assessment
- Justification for heavy-duty rating
- Description of patient's occupational or ADL demands
- Explanation of why ProHensor VC is appropriate choice

Clinical Notes

- Patient's activity level and lifestyle requirements
- Prior prosthetic history (if applicable)
- Functional goals and expected outcomes

Invoice/Pricing Documentation

- Itemized billing for ProHensor VC
- HCPCS code **L6722** clearly indicated

Claim Submission Process

Step 1: Verify PDAC Status
Contact Marins Inc. (Admin@MarinsMed.com) to confirm current PDAC verification status for **L6722** coverage.

Step 2: Obtain Prior Authorization (if required)
Check with payer regarding prior authorization requirements. Submit clinical documentation before device delivery when required.

Step 3: Submit Complete Documentation
Include all required documentation with claim submission:

- Physician prescription
- Letter of medical necessity
- Clinical evaluation notes
- Invoice with **L6722** code

Step 4: Follow Up
Monitor claim status and respond promptly to any requests for additional information.

Coding Tips

- Use **L6722** as the primary code for ProHensor VC
- Include appropriate modifiers as required by payer (e.g., RT/LT for right/left)
- Do not bundle VCAL Cartridge with **L6722** claim (bill separately under **L7499** if applicable)
- Ensure documentation clearly establishes heavy-duty rating medical necessity

---

If Billing Is Denied: ProHensor® VC

If reimbursement for ProHensor VC under **L6722** is denied, consider the following steps to support an appeal:

Common Denial Reasons

Denial Reason	Resolution Strategy
Lack of PDAC verification	Confirm PDAC status with Marins Inc.; provide verification number if available
Insufficient medical necessity	Submit additional clinical documentation; emphasize occupational demands and activity level
Heavy-duty rating not justified	Provide detailed description of patient's work/ADL requirements; document environmental factors
Prior authorization not obtained	Submit retro-authorization request with complete documentation
Incomplete documentation	Resubmit with all required elements; use checklist to ensure completeness

Appeal Documentation

Include the following in your appeal:

1. **Formal appeal letter** addressing specific denial reason
2. **Enhanced letter of medical necessity** with additional clinical detail
3. **Physician prescription** with clear heavy-duty designation
4. **Functional assessment** documenting patient's specific needs
5. **Photos or videos** (if helpful) showing patient's work environment or activities
6. **Comparison documentation** explaining why lighter-duty devices are insufficient
7. **PDAC verification information** (when available)

Appeal Letter Key Points

Your appeal should emphasize:

- Patient's specific occupational or lifestyle demands
- Clinical rationale for heavy-duty rating
- Proprioceptive feedback necessity for patient's functional goals
- Durability requirements based on patient's activities
- Field-serviceability benefits for long-term success
- Risk of prosthetic abandonment with inappropriate device

Contact Support

For assistance with denied claims:

- **Marins Inc. Reimbursement Support:** Admin@MarinsMed.com
- **PDAC Contractor:** https://www.dmepdac.com/contact
- **Payer Appeals Department:** Contact information on denial letter

---

Sample Letter of Medical Necessity: ProHensor® VC

[Prosthetist's Clinic Letterhead]

[Date]

[Insurance Company Name]
[Claims Department Address]
[City, State ZIP]

Re: Letter of Medical Necessity for ProHensor® VC Terminal Device
Patient: [Patient Full Name]
Policy #: [Insurance Policy Number]
Date of Birth: [Patient DOB]
Diagnosis: [ICD-10 Code and Description]

To Whom It May Concern:

I am writing to request authorization and reimbursement for a ProHensor® VC terminal device, a heavy-duty, body-powered, voluntary-closing prosthetic terminal device. This device is being prescribed for my patient, [Patient Name], an upper-limb amputee who requires a prosthesis that supports demanding occupational activities and provides reliable proprioceptive feedback for grip control.

Patient Background:
[Patient Name] is a [age]-year-old [occupation] with [amputation level] amputation of the [right/left] upper extremity. The patient requires a prosthetic terminal device that can withstand the demands of [his/her] occupation and daily activities, which include [specific activities: construction work, mechanical repair, power tool use, etc.].

Clinical Justification:

The ProHensor VC is medically necessary for this patient based on the following clinical factors:

Heavy-Duty Rating Required:
My patient performs medium to heavy-duty activities including [list specific activities]. These activities require a terminal device rated for industrial use that can withstand vibration, harsh environments (dirt, moisture, sawdust), and sustained repetitive use. Standard light-duty terminal devices are clinically inappropriate and would not provide adequate durability for this patient's needs.

Proprioceptive Feedback Essential:
The ProHensor VC's cable-based voluntary-closing mechanism provides critical proprioceptive feedback that allows the patient to modulate grip force in real time. This is essential for [patient's name]'s work, which requires both powerful grip for heavy objects and precise control for delicate tasks. This feedback reduces the risk of accidental drops and enables safer, more efficient task performance.

Field-Serviceability Critical:
Given the patient's occupational demands, the ProHensor VC's field-serviceable design is medically necessary to

minimize downtime. The patient relies on the prosthesis for employment and cannot tolerate extended periods without a functional device due to factory repairs.

Compatibility and Integration:
The ProHensor VC integrates with the patient's existing body-powered harness system, making it the most appropriate choice without requiring complete prosthetic system replacement.

Functional Goals:
With the ProHensor VC, the patient will be able to:

- Safely operate hand and power tools required for [occupation]
- Perform lifting, carrying, and material handling tasks
- Work in harsh environmental conditions
- Maintain employment and occupational independence
- Achieve improved quality of life and functional outcomes

Alternative Devices Considered:
Light-duty voluntary-closing devices: Insufficient durability for patient's occupational demands
Myoelectric devices: Not appropriate due to [environmental factors, battery dependence, patient preference for proprioceptive feedback, etc.]

Billing Information:

Device: ProHensor® VC Terminal Device

HCPCS Code: L6722 – Terminal Device, Hook or Hand, Heavy Duty, Mechanical, Voluntary Closing

PDAC Status: [Insert current status or "Please contact Marins Inc. for verification"]

Invoice: [Attach itemized invoice]

Based on comprehensive clinical evaluation and the patient's specific functional requirements, I believe the ProHensor VC is the most appropriate and medically necessary terminal device for this patient. The heavy-duty rating, proprioceptive feedback, and field-serviceability are all clinically essential features for successful prosthetic outcomes.

Please contact me directly if further documentation or clarification is needed.

Sincerely,

[Prosthetist Name, Credentials]
[License Number]
[Clinic Name]
[Phone Number]
[Email Address]

PART 2: VCAL Cartridge (L7499)

Component Overview

The VCAL (Voluntary Closing with Auto-Locking) Cartridge is a proprietary, field-replaceable component that transforms the ProHensor VC into a locking-capable terminal device. This modular cartridge adds advanced functionality that significantly enhances patient safety, reduces fatigue, and expands functional capabilities.

Design Features

Auto-Locking Mechanism
The VCAL Cartridge provides user-controlled locking that maintains grip without continuous cable tension. Once engaged, the lock holds securely until the user chooses to release, eliminating the need for sustained harness loading.

Three Operational Modes

Mode	Function	Use Cases
Wide Grip	Large diameter opening for power tools and large objects	Operating drills, holding lumber, gripping tool handles
Narrow Grip	Precise manipulation of smaller objects	Threading bolts, handling electronics, fine motor tasks
VC-Only Mode	Disengages locking for dynamic grip modulation	Repetitive tasks requiring quick release, assembly work

Field-Replaceable Design
The VCAL Cartridge can be installed or replaced by a certified prosthetist or informed user following Marins Inc. instructions. This modularity allows:

- Initial purchase with ProHensor VC
- Future upgrade of existing ProHensor VC
- Replacement when cartridge experiences wear over time
- Quick restoration of locking function without full device replacement

Universal ProSeries Compatibility
Compatible with all ProSeries terminal devices, providing consistent locking functionality across the product line.

Clinical Benefits & Medical Necessity

The VCAL Cartridge addresses critical clinical challenges that contribute to prosthetic abandonment and patient complications. When added to the ProHensor VC, it provides clinically significant benefits that improve patient outcomes and long-term device acceptance.

1. Enhanced Safety

Clinical Concern: Grip failures during critical tasks pose safety risks, particularly in occupational settings.

How VCAL Addresses This:

- Maintains secure grip without continuous user effort
- Reduces risk of accidental drops during tool operation
- Provides reliable hold during material handling
- Enables safer handling of heavy or hazardous objects
- Prevents grip failures during distraction or multitasking

Clinical Impact: Reduced workplace injuries, increased confidence in prosthetic function, improved safety compliance in occupational settings.

---

2. Prevention of Overuse Injuries and Fatigue Reduction

Clinical Concern: Continuous cable tension required by standard voluntary-closing devices causes cumulative strain on the shoulder, back, and residual limb. This leads to overuse injuries, chronic pain, and eventual prosthetic abandonment.

How VCAL Addresses This:

- Eliminates need for continuous cable tension during sustained grip tasks
- Reduces shoulder girdle loading and compensatory movement patterns
- Prevents development of repetitive strain injuries
- Enables longer work periods without cumulative fatigue
- Reduces residual limb discomfort from prolonged harness pressure

Clinical Impact: Prevention of secondary musculoskeletal complications, improved long-term prosthetic tolerance, reduced abandonment risk, enhanced occupational endurance.

Evidence-Based Rationale:
Research consistently identifies fatigue and discomfort as primary reasons for prosthetic abandonment. The VCAL Cartridge directly addresses this barrier by reducing the physical demand of sustained grip tasks.

---

3. Reduced Cognitive Load

Clinical Concern: Maintaining grip with standard VC devices requires constant attention and mental effort, limiting the user's ability to focus on task execution.

How VCAL Addresses This:

- User focuses on task completion rather than grip maintenance
- Enables multitasking while maintaining secure hold
- Reduces mental fatigue during complex work activities
- Allows more natural attention allocation during ADLs
- Improves efficiency in cognitively demanding occupational tasks

Clinical Impact: Enhanced task performance, reduced mental exhaustion, improved work efficiency, better quality of life during daily activities.

---

4. Expanded Functional Working Envelope

Clinical Concern: Standard VC devices require continuous tension, limiting the user's ability to maintain grip while positioning the arm in ergonomically challenging positions.

How VCAL Addresses This:

- Enables close-to-body gripping with sustained hold
- Reduces need for compensatory shoulder and trunk movements
- Allows lifting, carrying, and tool use in confined spaces
- Improves posture during prolonged tasks
- Increases efficiency by expanding functional reach while maintaining grip

Clinical Impact: Improved ergonomics, reduced compensatory movement patterns, enhanced functional independence, better postural health.

---

5. Task Versatility with Three Operational Modes

Clinical Concern: Different tasks require different grip approaches. Standard devices lack adaptability.

How VCAL Addresses This:

- Wide Grip mode for large objects and power tools
- Narrow Grip mode for precision work and small objects
- VC-Only mode when dynamic grip modulation is needed
- Quick mode switching without tools or adjustments
- Seamless adaptation to varied task demands

Clinical Impact: Single device meets multiple functional needs, reduced need for device changes, improved task efficiency, enhanced user satisfaction.

Medical Necessity: Who Benefits from VCAL

VCAL is Clinically Indicated When Patient:

- Performs sustained grip tasks (carrying, holding tools, prolonged grasping)
- Works in industrial, trade, or hands-on professions requiring reliable grip
- Has experienced or is at risk for fatigue-related complications with previous devices
- Requires multitasking capability while maintaining grip
- Needs to maintain grip in ergonomically challenging positions
- Demonstrates risk factors for prosthetic abandonment (previous device rejection, fatigue complaints, limited functional use)
- Performs medium to heavy-duty ADLs regularly
- Has occupational safety requirements for secure grip
- Reports difficulty with sustained grip using standard VC devices

Clinical Recommendation

For most active users, particularly those with occupational demands, the ProHensor VC + VCAL Cartridge combination provides optimal functional outcomes. Prescribing both components at initial fitting:

- Prevents overuse injuries before they develop
- Maximizes functional independence from the start
- Reduces cognitive burden during task learning
- Enhances workplace safety immediately
- Improves long-term device acceptance and reduces abandonment risk

---

HCPCS Coding for VCAL Cartridge

Suggested Code: L7499

L7499: UPPER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED

Code Justification

The VCAL Cartridge is appropriately coded under **L7499** because:

No Existing Code Describes This Functionality:
No current HCPCS code accounts for:

- Add-on components that transform VC devices into locking-capable systems
- Auto-locking mechanisms for voluntary-closing terminal devices
- Three-mode operational capability in mechanical devices
- Field-replaceable locking cartridges

Beyond L6722 Predicate:
L6722 describes voluntary-closing devices without locking mechanisms. The VCAL Cartridge adds functionality that exceeds the **L6722** definition, making it a separate component requiring separate coding.

Novel Technology:
The VCAL Cartridge represents proprietary, patented technology not represented by any existing classified HCPCS code. **L7499** is the appropriate designation for innovative prosthetic components awaiting potential future code assignment.

Why Not L6722?

L6722 explicitly describes "voluntary closing" devices. While the VCAL Cartridge works with VC devices, its primary function is providing auto-locking capability, which is distinct from standard voluntary closing operation. Billing VCAL under **L6722** would:

- Misrepresent the component's function
- Fail to capture the novel locking technology
- Potentially result in denial for exceeding code description
- Not account for the additional clinical value provided

Why PDAC Is Not Required for VCAL

L7499 is a Non-Specified Code

L7499 is designated as "not otherwise specified," meaning it covers prosthetic components that do not fit into existing predefined HCPCS classifications. By definition, non-specified codes:

- Do not have predefined product specifications
- Do not require PDAC verification
- Rely on medical necessity documentation instead of product verification

Documentation Replaces PDAC

Instead of PDAC verification, **L7499** claims require comprehensive documentation demonstrating:

- What the component does (auto-locking mechanism with three modes)
- Why it is medically necessary (safety, fatigue prevention, cognitive load reduction, working envelope expansion)
- Why no existing code applies (novel locking technology)
- Patient-specific functional needs (occupational demands, sustained grip requirements)

The documentation burden is higher for L7499, but PDAC verification is not required or applicable.

Billing Guidelines: VCAL Cartridge

Documentation Requirements

Required Documentation for L7499:

More comprehensive documentation is essential for L7499 claims because the code is non-specified.

1. **Detailed Narrative Letter**
    - Comprehensive description of VCAL Cartridge functionality
    - Explanation of auto-locking mechanism
    - Description of three operational modes and their clinical utility
    - Clear statement of why no existing HCPCS code applies
2. **Physician Prescription with Locking Language**
    - Prescription must specify need for locking capability
    - Recommended wording: "Body-powered voluntary closing terminal device with integrated auto-locking mechanism (VCAL) for sustained grip capability. Patient requires locking function to maintain grip without continuous cable tension due to occupational demands including [specific tasks]. Standard voluntary closing devices without locking capability are insufficient for patient's functional needs."
3. **Letter of Medical Necessity from Prosthetist**
    - Clinical evaluation demonstrating need for locking capability
    - Emphasis on clinical benefits: safety, fatigue prevention, cognitive load reduction, working envelope expansion
    - Justification for why standard **L6722** device alone is insufficient
    - Documentation of occupational or lifestyle demands requiring sustained grip
    - Statement addressing risk factors for prosthetic abandonment

4. **Functional Assessment**
    - Specific activities requiring sustained grip
    - Documentation of fatigue or safety concerns with non-locking devices
    - Occupational demands and environmental factors
5. **Invoice/Pricing Documentation**
    - Itemized billing for VCAL Cartridge (separate from ProHensor VC if applicable)
    - HCPCS code **L7499** clearly indicated
    - Clear identification as "VCAL Cartridge" or "Locking Mechanism Cartridge"

Claim Submission Process

Step 1: Prepare Comprehensive Documentation
Gather all required documentation before claim submission. **L7499** claims with insufficient documentation have higher denial rates.

Step 2: Obtain Prior Authorization (if required)
Many payers require prior authorization for **L7499** due to the non-specified nature of the code. Submit complete documentation with prior authorization request.

Step 3: Submit Complete Package
Include all required documentation with claim:

- Physician prescription with locking capability language
- Detailed narrative letter
- Letter of medical necessity emphasizing clinical benefits
- Functional assessment
- Invoice with **L7499** code

Step 4: Be Prepared for Documentation Requests
Payers may request additional information for **L7499** claims. Respond promptly with supplemental documentation as needed.

Coding Tips

- Use **L7499** as the code for VCAL Cartridge
- Include appropriate modifiers as required by payer (e.g., RT/LT for right/left)
- Bill separately from ProHensor VC (do not bundle)
- When billing both components together, submit as separate line items with individual justifications
- Emphasize the clinical necessity language: safety, fatigue prevention, cognitive load reduction, working envelope expansion
- Reference the three operational modes as evidence of unique functionality

---

If Billing Is Denied: VCAL Cartridge

Because **L7499** is a non-specified code, denials are more common than with established codes like **L6722**. However, strong documentation and persistent appeals often result in successful reimbursement.

Common Denial Reasons

Denial Reason	Resolution Strategy

Insufficient medical necessity	Emphasize clinical benefits (safety, fatigue prevention, cognitive load, working envelope); provide additional physician documentation
Not covered benefit	Cite prosthetic coverage policy; explain VCAL as prosthetic component; reference **L7499** as appropriate code for novel technology
Experimental/investigational	Document FDA Class I status; explain established use in O&P field; provide clinical evidence of functional benefits
No existing code justification unclear	Provide detailed comparison showing why **L6722** does not apply; emphasize locking mechanism as distinct functionality
Bundled with terminal device	Clarify VCAL is separate add-on component; reference modular design; explain separate billing is appropriate

Appeal Documentation

Include the following in your appeal:

1. **Formal appeal letter** addressing specific denial reason
2. **Enhanced letter of medical necessity** with extensive clinical detail about locking mechanism necessity
3. **Physician prescription** with explicit locking capability language
4. **Functional assessment** documenting patient's specific sustained grip needs
5. **Clinical evidence** regarding overuse injuries, fatigue, and prosthetic abandonment prevention
6. **Comparison documentation** explaining why standard **L6722** devices are insufficient
7. **Safety documentation** if applicable to patient's occupation
8. **Photos or videos** showing patient's work environment or sustained grip tasks (if helpful)

Appeal Letter Key Points

Your appeal should emphasize:

- Auto-locking mechanism is medically necessary for patient's specific functional needs
- Clinical benefits that prevent complications: safety, overuse injury prevention, fatigue reduction
- Why standard voluntary-closing devices (**L6722**) without locking are insufficient
- Three operational modes provide unique functionality not available in existing devices
- Field-replaceable design supports long-term prosthetic success
- Addressing abandonment risk factors through improved function
- Patient's occupational or lifestyle demands requiring sustained grip capability

Persistence Often Succeeds

L7499 denials are common initially because the code is non-specified and payers may be unfamiliar with VCAL technology. However:

- Many denials are overturned on appeal with comprehensive documentation
- Establishing precedent with a payer can facilitate future claims
- Peer-to-peer review with medical director can be effective
- Consider requesting Independent Medical Review if available

Contact Support

For assistance with denied claims:

- **Marins Inc. Reimbursement Support:** Admin@MarinsMed.com
- **Payer Appeals Department:** Contact information on denial letter

- **State Insurance Commissioner:** For dispute resolution assistance

---

Sample Letter of Medical Necessity: VCAL Cartridge

[Prosthetist's Clinic Letterhead]

[Date]

[Insurance Company Name]
[Claims Department Address]
[City, State ZIP]

Re: Letter of Medical Necessity for VCAL Cartridge
Patient: [Patient Full Name]
Policy #: [Insurance Policy Number]
Date of Birth: [Patient DOB]
Diagnosis: [ICD-10 Code and Description]

To Whom It May Concern:

I am requesting reimbursement for a VCAL (Voluntary Closing with Auto-Locking) Cartridge for use with the ProHensor® terminal device, a body-powered upper-limb prosthesis used by my patient, [Patient Name].

Component Description:

The VCAL Cartridge is a field-replaceable internal component that provides an auto-locking mechanism for voluntary-closing terminal devices. This component is essential to address critical clinical needs that standard voluntary-closing devices cannot meet.

Patient Background:

[Patient Name] is a [age]-year-old [occupation] with [amputation level] amputation of the [right/left] upper extremity. The patient's daily activities and occupational demands include [specific tasks: sustained grip tasks, tool operation, material handling, etc.]. These activities require sustained grip capability that exceeds what standard voluntary-closing devices can provide without causing fatigue and overuse complications.

Clinical Justification - Medical Necessity:

The VCAL Cartridge is medically necessary for this patient based on the following critical clinical factors:

1. Enhanced Safety:
My patient's occupation requires secure, reliable grip during [specific tasks]. The auto-locking mechanism maintains grip without continuous user effort, reducing the risk of accidental drops that could cause workplace injuries. Standard voluntary-closing devices without locking capability create safety concerns during [specific activities] because grip failures can occur during distraction or fatigue.

2. Prevention of Overuse Injuries and Fatigue Reduction:
Standard voluntary-closing devices require continuous cable tension to maintain grip, resulting in sustained loading of the shoulder girdle, back, and residual limb. This patient performs [number] hours per day of sustained grip tasks. Without the VCAL locking mechanism, this continuous tension will lead to:

- Shoulder and back overuse injuries
- Chronic residual limb discomfort
- Compensatory movement patterns causing secondary complications
- Cumulative fatigue limiting work capacity

The VCAL Cartridge eliminates continuous cable tension during sustained grip tasks, preventing these predictable complications. This is not a convenience feature - it is medically necessary to prevent secondary musculoskeletal injuries.

3. Reduced Cognitive Load:
My patient's work requires [complex tasks, multitasking, safety-critical attention]. Standard voluntary-closing devices require constant mental attention to maintain grip, limiting the patient's ability to focus on task execution. The VCAL locking mechanism allows the patient to focus cognitive resources on work performance rather than grip maintenance, which is essential for [occupational safety, productivity, quality of work].

4. Expanded Functional Working Envelope:
The patient requires the ability to maintain grip while positioning the arm in various positions for [specific tasks]. Standard voluntary-closing devices without locking severely limit this capability because continuous cable tension restricts arm positioning. The VCAL Cartridge enables close-to-body gripping with sustained hold, reducing compensatory shoulder movements and improving ergonomics during [lifting, carrying, tool use in confined spaces, etc.].

5. Three Operational Modes for Task Versatility:
The VCAL Cartridge provides three operational modes that are clinically necessary for this patient's varied activities:

- **Wide Grip Mode:** For large objects and power tools used in [specific tasks]
- **Narrow Grip Mode:** For precision work including [specific tasks]
- **VC-Only Mode:** For repetitive tasks requiring dynamic grip modulation

This versatility allows a single device to meet multiple functional needs, reducing the need for device changes and improving efficiency.

Why Standard L6722 Devices Are Insufficient:

Standard voluntary-closing terminal devices (HCPCS **L6722**) do not include locking mechanisms. For this patient:

- Sustained grip tasks would require continuous cable tension for [X] hours per day
- This continuous tension will predictably cause overuse injuries
- The patient has already experienced [fatigue, discomfort, safety concerns] with non-locking devices
- Standard VC devices do not provide the safety, endurance, or cognitive load reduction this patient requires

HCPCS Code Justification:

The VCAL Cartridge is appropriately coded as **L7499** (Upper Extremity Prosthesis, Not Otherwise Specified) because:

- No existing HCPCS code describes auto-locking mechanisms for voluntary-closing devices
- The locking functionality exceeds the **L6722** predicate device definition
- The three operational modes represent novel functionality not captured by existing codes
- **L7499** is the appropriate classification for innovative prosthetic components without dedicated codes

Addressing Prosthetic Abandonment Risk:

Research consistently identifies fatigue and discomfort as primary reasons for prosthetic abandonment. This patient demonstrates risk factors including [high activity demands, previous device dissatisfaction, occupational requirements]. The VCAL Cartridge directly addresses these abandonment risk factors by reducing physical and cognitive burden, making long-term prosthetic success significantly more likely.

Functional Goals:

With the VCAL Cartridge, the patient will be able to:

- Safely perform sustained grip tasks without fatigue
- Work full shifts without developing overuse complications
- Maintain grip while multitasking and focusing on work quality
- Perform ergonomically demanding tasks with proper positioning
- Achieve long-term prosthetic acceptance and functional independence

Alternative Devices Considered:

Standard voluntary-closing devices without locking: Clinically inappropriate due to fatigue and overuse injury risk
Myoelectric devices: Not suitable due to [environmental factors, battery dependence, proprioceptive feedback need, etc.]

Billing Information:

- **Component:** VCAL (Voluntary Closing with Auto-Locking) Cartridge
- **Device:** ProHensor® Terminal Device
- **HCPCS Code: L7499** – Upper Extremity Prosthesis, Not Otherwise Specified
- **Invoice:** [Attach itemized invoice]

Summary:

The VCAL Cartridge is not an optional enhancement - it is medically necessary to provide safe, sustainable prosthetic function for this patient. The auto-locking mechanism prevents predictable overuse injuries, enhances safety, reduces cognitive burden, and expands functional capability in ways that standard **L6722** devices cannot achieve. This component directly addresses known barriers to prosthetic abandonment and is essential for long-term success.

This component is clinically appropriate and medically necessary to maintain the patient's functional independence, occupational capacity, and quality of life. Please contact me with any questions or requests for additional documentation.

Sincerely,

[Prosthetist Name, Credentials]
[License Number]
[Clinic Name]
[Phone Number]
[Email Address]

PART 3: Combined System (VC + VCAL)

Clinical Rationale for Prescribing Both Together

While the ProHensor VC is a complete, functional terminal device on its own, prescribing it with the VCAL Cartridge at initial fitting provides optimal clinical outcomes for most active users with occupational demands.

Why Prescribe Both Components Together

Immediate Clinical Benefits:

- Safety, fatigue prevention, cognitive load reduction, and working envelope expansion from day one
- No adaptation period to locking function - patient learns device with all capabilities available
- Prevents development of compensatory patterns that occur when using non-locking devices
- Addresses abandonment risk factors before they contribute to device rejection

Prevents Delayed Complications:

- Overuse injuries develop gradually over weeks/months of continuous cable tension
- Early intervention with VCAL prevents these predictable complications
- Addressing fatigue and strain early improves long-term prosthetic tolerance
- Proactive approach is more effective than reactive upgrade after problems develop

Maximizes Functional Independence:

- Patient has full capability for varied task demands immediately
- Three operational modes support learning and adaptation across activities
- Enhanced safety supports confidence during prosthetic training
- Optimal function from the start improves patient satisfaction and outcomes

Cost-Effectiveness:

- Single fitting and training session for complete system
- Avoids cost of second fitting if VCAL added later
- Prevents medical costs associated with overuse injuries
- Reduces risk of device abandonment requiring alternative solutions

Clinical Decision Framework

Strongly Recommend Both Components When Patient:

- Has occupational demands or regular sustained grip requirements
- Works in industrial, trade, or hands-on professions
- Demonstrates any risk factors for prosthetic abandonment
- Has history of fatigue or discomfort with previous devices
- Requires maximum safety and reliability
- Performs medium to heavy-duty ADLs regularly

ProHensor VC Alone May Be Appropriate When Patient:

- Primarily performs dynamic, varied grip tasks without sustained hold requirements
- Has limited sustained grip needs in daily activities
- Wants to evaluate base technology before adding VCAL
- Has budget constraints at initial fitting (with clear plan to add VCAL when feasible)

Important Note: Even when budget constraints exist, clinicians should document the clinical benefit of adding VCAL and establish a timeline for upgrade to optimize patient outcomes.

Billing Strategy for Combined Purchase

When prescribing ProHensor VC and VCAL Cartridge together at initial fitting, bill as two separate components with individual justifications.

Billing Structure

Component 1: ProHensor® VC

- **HCPCS Code: L6722**
- **Justification:** Heavy-duty voluntary-closing terminal device for patient's occupational/ADL demands
- **Documentation:** Standard **L6722** requirements (see Part 1)

Component 2: VCAL Cartridge

- **HCPCS Code: L7499**
- **Justification:** Auto-locking mechanism medically necessary for safety, fatigue prevention, cognitive load reduction, working envelope expansion
- **Documentation:** Comprehensive **L7499** requirements (see Part 2)

Documentation Strategy

Each component requires separate justification:

For L6722 (ProHensor VC):

- Document need for heavy-duty voluntary-closing device
- Justify proprioceptive feedback requirement
- Explain occupational or ADL demands requiring durable mechanical device

For L7499 (VCAL Cartridge):

- Document need for auto-locking capability specifically
- Emphasize clinical benefits: safety, overuse injury prevention, fatigue reduction, cognitive load reduction, working envelope expansion
- Explain why standard **L6722** device alone is insufficient
- Detail sustained grip requirements and occupational demands

Combined narrative should demonstrate:

- Patient requires both heavy-duty VC foundation AND locking capability

- Each component addresses distinct clinical needs
- Complete system provides optimal functional outcomes
- Both components together prevent prosthetic abandonment

Physician Prescription Language

Recommended prescription wording for combined system:

"Body-powered voluntary closing terminal device with integrated auto-locking mechanism (VCAL) for sustained grip capability. Patient requires:

1. Heavy-duty voluntary-closing terminal device (HCPCS **L6722**) with proprioceptive feedback for occupational demands including [specific tasks]
2. Auto-locking mechanism (HCPCS **L7499**) to maintain grip without continuous cable tension, preventing overuse injuries and fatigue during sustained grip tasks including [specific tasks]

Standard voluntary closing devices without locking capability are insufficient for patient's functional needs due to [occupational safety requirements, sustained grip demands, overuse injury risk, etc.]."

Claim Submission Process

Step 1: Verify PDAC Status for ProHensor VC
Contact Marins Inc. (Admin@MarinsMed.com) for current **L6722** PDAC verification status.

Step 2: Obtain Prior Authorization (if required)
Submit prior authorization request with complete documentation for both components. Some payers require prior auth for **L7499** specifically.

Step 3: Submit as Separate Line Items

Line Item 1: ProHensor VC, **L6722**, [price]

Line Item 2: VCAL Cartridge, **L7499**, [price]

Step 4: Include Complete Documentation Package

- Physician prescription with both components clearly specified
- Letter of medical necessity covering both components (see sample letter in this section)
- Separate clinical justifications for **L6722** and **L7499**
- Functional assessment documenting need for both
- Itemized invoice showing separate components

Step 5: Follow Up Actively
Monitor claim status for both components. If one is approved and one denied, appeal the denial with supplemental documentation.

Common Payer Questions

"Why are you billing two codes for one device?"
Response: The ProHensor VC (L6722) is the heavy-duty voluntary-closing terminal device. The VCAL Cartridge (L7499) is a separate add-on component that provides auto-locking functionality not included in standard **L6722** devices. Each component provides distinct clinical benefits and is appropriately billed separately.

"Can't this be bundled under L6722?"
Response: No. **L6722** specifically describes voluntary-closing devices without locking mechanisms. The VCAL Cartridge adds functionality beyond the **L6722** definition and is appropriately coded as **L7499** due to its novel locking technology.

"Is the locking mechanism medically necessary or just a convenience?"
Response: The locking mechanism is medically necessary to prevent overuse injuries, enhance safety, reduce cognitive load, and expand functional working envelope. These are not convenience features - they are clinical interventions that prevent predictable complications and prosthetic abandonment. [Provide patient-specific examples from documentation.]

Sample Letter of Medical Necessity: Combined System

[Prosthetist's Clinic Letterhead]

[Date]

[Insurance Company Name]
[Claims Department Address]
[City, State ZIP]

Re: Letter of Medical Necessity for ProHensor® VC + VCAL Cartridge
Patient: [Patient Full Name]
Policy #: [Insurance Policy Number]
Date of Birth: [Patient DOB]
Diagnosis: [ICD-10 Code and Description]

To Whom It May Concern:

I am writing to request authorization and reimbursement for a complete ProHensor® prosthetic terminal device system consisting of two components:

1. ProHensor® VC (Voluntary Closing) terminal device – HCPCS **L6722**
2. VCAL (Voluntary Closing with Auto-Locking) Cartridge – HCPCS **L7499**

This complete system is being prescribed for my patient, [Patient Name], an upper-limb amputee who requires both heavy-duty voluntary-closing functionality AND auto-locking capability to achieve safe, sustainable prosthetic function.

Patient Background:

[Patient Name] is a [age]-year-old [occupation] with [amputation level] amputation of the [right/left] upper extremity. The patient's occupational and daily activities include [specific sustained grip tasks, tool operation, material handling, etc.]. These demands require a prosthetic system that provides both durable mechanical function and sustained grip capability without causing fatigue or overuse complications.

Clinical Justification - Why Both Components Are Medically Necessary:

This patient requires a complete prosthetic system that addresses multiple clinical needs. Each component provides distinct, essential functionality:

Component 1: ProHensor® VC Terminal Device (L6722)

The ProHensor VC provides the foundational heavy-duty voluntary-closing capability required for this patient:

- **Heavy-Duty Rating:** Patient performs industrial/occupational tasks requiring durable device rated for medium to heavy ADLs
- **Proprioceptive Feedback:** Cable-based VC mechanism provides essential force feedback for grip control and safety
- **Environmental Durability:** Work environment includes [dirt, moisture, vibration, harsh conditions] requiring robust construction
- **Mechanical Reliability:** Patient requires device without electronic failure points for occupational dependence
- **Field-Serviceability:** Quick maintenance capability is medically necessary to minimize work interruption

Why L6722 Device Is Medically Necessary:
Standard light-duty devices and myoelectric options are clinically inappropriate for this patient's demands. The heavy-duty VC foundation is essential, but alone is insufficient for optimal outcomes.

Component 2: VCAL Cartridge (L7499)

The VCAL Cartridge adds critical auto-locking functionality that transforms the device's clinical utility:

1. Enhanced Safety (Medical Necessity):
Patient's occupation involves [specific safety-critical tasks]. Auto-locking mechanism maintains grip during [tool operation, material handling, etc.] without continuous user effort, preventing accidental drops that could cause workplace injuries. This is not optional - it is required for occupational safety compliance.

2. Prevention of Overuse Injuries (Medical Necessity):
Patient performs [X] hours per day of sustained grip tasks. Standard **L6722** devices require continuous cable tension, resulting in:

- Predictable shoulder girdle overuse injuries
- Chronic back strain from compensatory postures
- Residual limb complications from sustained harness pressure
- Progressive fatigue limiting work capacity

The VCAL locking mechanism eliminates continuous cable tension during sustained tasks, preventing these complications. This is preventive medical intervention, not enhancement.

3. Reduced Cognitive Load (Medical Necessity):
Patient's work requires [complex operations, safety attention, quality control]. Standard VC devices demand constant mental attention to grip maintenance. VCAL locking allows cognitive focus on work performance rather than grip, which is essential for [occupational safety, productivity, error prevention].

4. Expanded Functional Working Envelope (Medical Necessity):
Patient must maintain grip while positioning arm for [specific ergonomically demanding tasks]. Standard **L6722** devices severely limit this because continuous cable tension restricts positioning. VCAL enables close-to-body gripping with sustained hold, reducing compensatory movements and preventing secondary musculoskeletal complications.

5. Three Operational Modes (Medical Necessity):
Patient's varied activities require adaptability:

- **Wide Grip:** Power tools and large objects in [specific tasks]
- **Narrow Grip:** Precision work including [specific tasks]
- **VC-Only Mode:** Dynamic grip modulation for [repetitive tasks]

Why Standard L6722 Alone Is Insufficient:

A standard **L6722** device without locking would:

- Require continuous cable tension for [X] hours daily, causing predictable overuse injuries
- Create safety risks during [specific tasks] due to grip failures during fatigue or distraction
- Limit functional working envelope, reducing ergonomic options
- Increase cognitive burden, affecting work quality and safety
- Present high risk for prosthetic abandonment due to fatigue and discomfort

Why Complete System at Initial Fitting Is Optimal:

Prescribing both components together:

- Prevents overuse injury development from the start
- Provides maximum safety from day one of prosthetic use
- Avoids patient adaptation to compensatory patterns that develop without locking
- Reduces total healthcare costs by preventing complications
- Addresses prosthetic abandonment risk factors proactively
- Enables optimal functional outcomes immediately

Separate Coding Justification:

L6722 (ProHensor VC): Appropriate code for heavy-duty voluntary-closing terminal device foundation
L7499 (VCAL Cartridge): Appropriate code for auto-locking mechanism because no existing code describes this functionality

These are distinct components providing separate clinical benefits, appropriately billed as separate line items.

Functional Goals with Complete System:

With the ProHensor VC + VCAL Cartridge system, the patient will:

- Safely perform occupational tasks with reliable grip and reduced injury risk
- Work full shifts without developing overuse complications or fatigue
- Maintain grip while multitasking and focusing on work quality
- Perform ergonomically demanding tasks with proper positioning
- Achieve long-term prosthetic acceptance and functional independence
- Maintain employment and quality of life

Alternative Devices Considered:

Standard **L6722** without locking: Clinically inappropriate - will cause predictable overuse injuries and high abandonment risk
Light-duty VC devices: Insufficient durability for patient's demands
Myoelectric devices: Not suitable due to [environmental factors, battery limitations, etc.]

Billing Information:

- **Component 1:** ProHensor® VC Terminal Device | HCPCS Code: **L6722**
- **Component 2:** VCAL Cartridge | HCPCS Code: **L7499**
- **Invoice:** [Attach itemized invoice showing both components]

Summary:

This patient requires both the heavy-duty VC foundation (**L6722**) AND the auto-locking capability (**L7499**) to achieve safe, sustainable prosthetic function. Each component addresses distinct, medically necessary clinical needs. Together, they provide the complete functional capability this patient requires while preventing predictable complications and prosthetic abandonment.

Based on comprehensive clinical evaluation, the ProHensor VC + VCAL Cartridge system is the most appropriate and medically necessary prosthetic solution for this patient's functional requirements and long-term success.

Please contact me directly if further documentation or clarification is needed.

Sincerely,

[Prosthetist Name, Credentials]
[License Number]
[Clinic Name]
[Phone Number]
[Email Address]

Activities Where the Complete System Excels

The combination of ProHensor VC + VCAL Cartridge provides maximum functional capability across demanding activities. The auto-locking mechanism significantly enhances performance in sustained grip tasks while maintaining the proprioceptive feedback and durability of the VC base device.

Heavy-Duty Work & Daily Activities

Construction and Trades:

- Sustained holding of lumber, pipes, materials during positioning
- Power tool operation with secure grip (drills, saws, impact wrenches)
- Lifting and carrying heavy equipment without continuous tension
- Working at heights where grip security is safety-critical

Mechanical and Repair Work:

- Holding parts during assembly without fatigue
- Operating hand and power tools with reliable grip
- Working in confined spaces with ergonomic arm positioning
- Maintaining grip during complex multi-step procedures

Electrical and Plumbing:

- Threading conduit and pipes while maintaining hold
- Operating specialized tools with sustained grip

- Working overhead or in awkward positions
- Precision work requiring stable hold plus force modulation

Tasks Involving Vibration & Harsh Environments

Outdoor and Industrial Work:

- Jackhammer and pneumatic tool operation with secure locking grip
- Chainsaw use with safety-critical grip security
- Working in rain, dirt, sawdust without device degradation
- Landscaping with sustained tool and material handling

Manufacturing and Production:

- Assembly line work with repetitive sustained grip
- Material handling in harsh environments
- Quality control tasks requiring both precision and endurance
- Operating industrial equipment with vibration and environmental exposure

Sustained Grip for Strength & Endurance

Carrying and Lifting:

- Extended carrying of tools, equipment, materials to job sites
- Lifting and positioning heavy objects with secure hold
- Transporting items over distances without arm fatigue
- Maintaining grip while climbing, reaching, or positioning body

Prolonged Task Execution:

- Multi-hour projects requiring continuous grip capability
- Sustained material holding during lengthy procedures
- Work shifts requiring consistent grip performance without decline
- Endurance activities where fatigue prevention is critical

Precision, Versatility & Multitasking

Variable Object Handling:

- Wide Grip mode for large diameter tools and objects
- Narrow Grip mode for small fasteners, electronics, delicate items
- Rapid mode switching without interrupting workflow
- Single device meeting multiple task demands efficiently

Complex Work Requiring Focus:

- Maintaining grip while reading instructions or monitoring processes
- Secure hold during safety-critical attention to other factors
- Reduced mental fatigue enabling better work quality
- Multitasking capability improving productivity

Ergonomically Demanding Tasks:

- Close-to-body work improving posture and reducing strain
- Overhead work with sustained grip capability
- Confined space tasks where arm positioning is constrained
- Awkward position work with reduced compensatory movement requirements

Recreational and Daily Living

Active Recreation:

- Cycling with secure handlebar grip on extended rides
- Hiking with trekking pole use and sustained equipment carrying
- Camping and outdoor activities with reliable gear handling
- Sports and activities requiring endurance grip

Daily Living Tasks:

- Grocery shopping with sustained bag carrying
- Household projects and maintenance work
- Yard work including mowing, trimming, leaf management
- Cooking and food preparation with secure utensil holding

PART 4: General Information

Billing Code Context

Understanding the ProHensor® Billing Strategy

The ProHensor® system represents an innovative approach to body-powered prosthetics that combines proven voluntary-closing technology with novel auto-locking functionality. To optimize reimbursement success while protecting the advanced VCAL technology, Marins Inc. has structured the ProHensor® as two separately billable components.

Current HCPCS Landscape

L6722: Heavy-Duty Voluntary Closing Devices

The established base code for mechanical voluntary closing heavy-duty terminal devices covered by Medicare is **L6722**, which describes:

"Terminal device, hook or hand, heavy duty, mechanical, voluntary closing, any material, any size, lined or unlined."

This code represents:

- Voluntary-closing grip mechanism
- Heavy-duty construction
- Mechanical (non-powered) operation
- Does NOT include locking mechanisms

L7499: Not Otherwise Specified

L7499 is designated for upper extremity prosthetic components that do not fit into existing predefined HCPCS codes:

"Upper extremity prosthesis, not otherwise specified."

This code is appropriate when:

- Device features exceed predicate device specifications
- Novel technology or functionality is not represented by existing codes
- Component adds unique capabilities beyond standard classifications

Myoelectric Devices

Myoelectric devices fall under a different family of codes due to their powered, electronic function and are not relevant to the ProHensor® billing strategy.

ProHensor® Billing Structure

Two-Component System

Component 1: ProHensor® VC (Voluntary Closing)

- Suggested Code: **L6722**
- Functions as a heavy-duty voluntary-closing terminal device
- Meets all criteria for **L6722** classification
- Provides proprioceptive feedback through cable tension
- Durable, field-serviceable, mechanical operation

Component 2: VCAL Cartridge (Voluntary Closing with Auto-Locking)

- Suggested Code: **L7499**
- Adds auto-locking mechanism functionality
- Provides three operational modes (wide grip, narrow grip, VC-only)
- Represents novel technology not described by existing codes
- Transforms functional capability beyond **L6722** predicate

Strategic Rationale for Separate Billing

1. Market Access & Reimbursement Success

- **L6722** has established coverage under Medicare and most commercial payers
- Billing ProHensor VC under **L6722** provides clear reimbursement pathway
- Reduces initial claim denials and administrative burden
- Allows clinicians to prescribe proven technology with confidence

2. Protection of Novel VCAL Technology

- Auto-locking mechanism is proprietary and patented
- No existing HCPCS code adequately describes locking-capable VC devices
- **L7499** classification preserves unique functionality
- Positions VCAL for potential future dedicated HCPCS code assignment

3. Clinical Flexibility & Patient Choice

- Patients can purchase ProHensor VC alone if budget-constrained
- VCAL can be added at initial fitting or as future upgrade
- Allows phased approach when necessary
- However, clinical best practice is prescribing both together for optimal outcomes

4. Documentation of Medical Necessity

Separate billing allows clear documentation of:

- **L6722**: Need for heavy-duty voluntary closing with proprioceptive feedback
- **L7499**: Additional need for auto-locking to prevent fatigue, enhance safety, reduce cognitive load, expand working envelope

Until CMS Creates New Coding Guidance for VCAL Technology

The ProHensor® VC is a voluntary-closing terminal device appropriately classified under **L6722**. It functions as a complete, standalone heavy-duty VC device.

The VCAL Cartridge adds auto-locking capability that is not represented by any existing HCPCS code. No current code describes add-on components that transform voluntary-closing devices into locking-capable systems.

Current best practice:

- Bill the ProHensor VC under **L6722** (established heavy-duty VC device)
- Bill the VCAL Cartridge separately under **L7499** (novel locking technology)

Future possibility:
As VCAL technology gains adoption and clinical evidence demonstrates outcomes, CMS may create a dedicated HCPCS code specifically for "locking mechanism cartridges for voluntary-closing terminal devices" or similar classification. Until that time, **L7499** is the most appropriate code for the VCAL Cartridge.

Clinical and Billing Best Practices

For Optimal Patient Outcomes:

Prescribe ProHensor VC + VCAL Cartridge together whenever clinically indicated
Bill separately under **L6722** and **L7499** with complete documentation
Include physician prescription specifying need for locking capability
Provide detailed narrative explaining clinical necessity of both components

Documentation Should Demonstrate:

- **L6722** (ProHensor VC): Patient requires heavy-duty voluntary closing with proprioceptive feedback for occupational/ADL demands
- **L7499** (VCAL Cartridge): Patient additionally requires auto-locking mechanism to prevent overuse injuries and fatigue, enhance safety, reduce cognitive load, expand functional working envelope, and address risk factors for prosthetic abandonment

Comparison to Other Terminal Device Codes

Code	Description	ProHensor Application
L6722	Voluntary closing, heavy duty, mechanical, no locking	ProHensor VC base device
L6721	Voluntary closing, light duty	ProHensor exceeds light-duty rating
L6880-L6882	Myoelectric hands	ProHensor is mechanical, not powered
L7499	Not otherwise specified	VCAL Cartridge (novel locking technology)

Summary

The ProHensor® billing structure reflects both clinical reality and reimbursement strategy:

- ProHensor VC (**L6722**) provides the proven, reimbursable foundation
- VCAL Cartridge (**L7499**) adds clinically significant locking functionality
- Together, they address key barriers to prosthetic acceptance: fatigue, safety, cognitive load, and functional limitations
- Separate billing protects novel technology while ensuring reimbursement success

This approach enables clinicians to prescribe the complete, clinically optimal system while navigating current HCPCS coding limitations.

FDA Status

The ProHensor® is an FDA Class I medical device under Product Code IQZ (External Limb Prosthetic Component) and will be registered under 21 CFR § 890.3420.

As a Class I device, it is exempt from premarket notification [510(k)] but must comply with all applicable general controls, including establishment registration, labeling, and good manufacturing practices.

FDA establishment registration is currently in process.

For questions about regulatory status:
Marins Inc. | Admin@MarinsMed.com

ProHensor® Limited Warranty

Marins Inc. provides the following limited warranty coverage for the ProHensor® terminal device:

Warranty Coverage

Terminal Device (ProHensor VC):
24-month limited warranty against defects in materials and workmanship under normal use.

Replaceable Locking Cartridge (VCAL):
90-day limited warranty against manufacturing defects. Failures occurring within this period will be presumed to result from manufacturing defects unless there is evidence of use outside the conditions defined in the "Definition of Normal Use." Failures after 90 days will be presumed to result from normal wear unless a clear manufacturing defect is demonstrated. As a wear-dependent component, the cartridge's lifespan varies based on usage and is not subject to extended durability warranty coverage. It is designed to be field-serviceable and replaced as needed.

Fingers and External Components:
Considered wear-prone components and are not covered under this Limited Warranty.

Warranty Terms

If a covered defect or malfunction occurs during the warranty period and is not the result of exclusions outlined in the official documentation, Marins Inc. will, at its sole discretion, repair or replace the product or component with a new or reconditioned part of comparable function. All warranty determinations are made solely by Marins Inc.

This limited warranty supports long-term reliability and user satisfaction. It does not apply to damage caused by misuse, unauthorized modifications, or repairs that fall outside of published guidelines. Full terms and exclusions are outlined in the official warranty documentation.

Shipping Responsibilities

Customers are responsible for shipping the product to Marins Inc. for inspection. If the warranty applies, Marins Inc. will cover return shipping to the customer.

Definition of Normal Use

"Normal use" refers to operation of the ProHensor® as a body-powered terminal device in activities of daily living and moderate physical tasks. It assumes the device is used with appropriate prosthetic components and within the functional design limits as instructed by Marins Inc. or a certified prosthetist.

This includes:

- Daily household and occupational tasks such as lifting, grasping, manipulating objects, and recreational use appropriate for the device
- Use within environments typical of daily life and work settings

Normal use excludes:

- Activities that would cause damage to a biological limb (e.g., blunt force, crushing, high-torque tasks)
- Exposure to chemicals such as chlorine, salt, acid, or other corrosive agents
- Prolonged or extreme environmental exposure (e.g., temperatures below -5°C or above 50°C)
- Submersion in water; the device is not rated for submerged activity at this time

Exclusions

This warranty does not cover:

1. Normal wear and tear, including but not limited to surface scratches, scuffs, or cosmetic changes
2. The fingers of the ProHensor®
3. Use, fabrication, installation, or servicing outside of Marins' instructions or recommendations
4. Damage resulting from misuse, neglect, abuse, impact, or improper operation
5. Modifications made to the device or its components without prior written approval from Marins Inc., except as noted in "Authorized Service and Modifications"
6. Damage caused by exposure to chemicals, abrasives, or unsuitable environmental conditions
7. Prosthetic fitting or clinical services related to the device

Authorized Service and Modifications

The ProHensor® is designed with a modular locking cartridge (VCAL) that may be removed and replaced by a certified prosthetist or an informed end user in accordance with Marins' published instructions.

Any other modification, internal disassembly, or repair performed by anyone other than Marins Inc. or an authorized service provider—outside of published guidelines—will void this warranty.

Additional Terms and Limitations

Limitation of Liability:
To the maximum extent permitted by law, Marins Inc. shall not be liable for any incidental, indirect, special, or consequential damages arising from the use or inability to use the ProHensor®, even if advised of the possibility of such damages. Marins' total liability under this warranty shall not exceed the original purchase price of the product.

Proof of Purchase Required:
A valid proof of purchase from Marins Inc. or an authorized distributor is required for all warranty claims.

Non-Transferable Warranty:
This Limited Warranty applies to the original end user (the amputee) for whom the device was purchased, whether purchased directly or on their behalf by a prosthetist or clinic. It is not transferable to subsequent users.

Disclaimer of Implied Warranties:
Except as expressly stated herein, Marins Inc. disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose.

Full Warranty Available:
The complete ProHensor® Limited Warranty is available as a separate document. Please contact Marins Inc. or visit our website for more information.

Contact for Warranty Claims:
Marins Inc. | Admin@MarinsMed.com

Service & Maintenance Information

Field-Serviceability Design Philosophy

The ProHensor® was engineered not only for performance and durability but also for field-serviceability. Certain components are intentionally modular to allow for cost-effective maintenance and repair over the device's lifespan—without requiring full replacement.

ProHensor VC Maintenance

Routine Maintenance:

- Cleaning and inspection following manufacturer guidelines
- Cable tension adjustment as needed
- Routine component checks by prosthetist
- Lubrication per published maintenance schedule

Field-Serviceable Components:

- Standard prosthetic components (cables, housing, wrist units)
- Finger replacements when worn
- Routine adjustments and alignments

Benefits:

- Minimizes downtime for users dependent on device
- Reduces long-term ownership costs
- Extends device lifespan through preventive maintenance
- Supports occupational users requiring continuous function

VCAL Cartridge Replacement

Important Billing Note:
The Replaceable VCAL Cartridge is not intended to be billed during the initial device claim when purchased with ProHensor VC. It is considered a future maintenance item and should only be submitted for reimbursement as a repair or replacement if mechanical wear occurs over time.

VCAL Cartridge Overview:

The replaceable VCAL Cartridge is a proprietary, patented component that restores the ProHensor®'s auto-locking function when wear occurs. It is not part of the initial billing when purchased with the device and should not be submitted to payers as a separate reimbursable line item at the time of original device delivery (unless being added as an upgrade to an existing ProHensor VC).

However, it may be eligible for reimbursement as a repair or replacement component if the device experiences mechanical wear or functional failure over time.

Key Features:

- Field-replaceable by prosthetist or informed user
- Restores full locking function and gripping capability
- Reduces downtime, extending the life of the terminal device
- Compatible with all ProHensor® models
- Designed for routine maintenance and long-term serviceability

Billing Guidance for VCAL Cartridge Repairs

When VCAL Cartridge replacement is needed due to wear:

Until a unique code is established, the most appropriate HCPCS code is:

L7499 – Upper Extremity Prosthesis, Not Otherwise Specified
(For future repairs/replacements only – not to be used for initial device billing when purchased with ProHensor VC.)

When submitting for reimbursement of a VCAL Cartridge replacement, include:

- Letter of medical necessity from the prosthetist
- Documentation of locking mechanism failure or wear
- Explanation of user need (e.g., work environment, safety concerns)
- Justification for repair over full device replacement
- Pricing/invoice documentation as required by payer
- Evidence of prior authorization of original VCAL Cartridge (if applicable)

Maintenance Schedule Recommendations

Monthly:

- Visual inspection for wear or damage
- Cleaning per manufacturer guidelines
- Cable tension check

Quarterly:

- Comprehensive functional assessment
- Component wear evaluation
- Lubrication and adjustment as needed

Annually:

- Professional prosthetist evaluation
- Comprehensive maintenance service
- Documentation of device condition for warranty purposes

Contact for Service Support

For maintenance guidance, service questions, or replacement parts:
Marins Inc. | Admin@MarinsMed.com

APPENDICES

Appendix A: Coding Descriptors

L6722 - ProHensor® VC Justification

The ProHensor® VC is a body-powered, mechanical voluntary-closing terminal device designed for upper-limb amputees at the wrist or higher. It provides grip modulation with proprioceptive feedback, enabling users to control grip force through cable tension.

Heavy-Duty Rating:
Designed for high-strength applications, the ProHensor VC is built for industrial, trade, and hands-on professions, including construction, mechanical work, and manual labor. Rated for medium to heavy activities of daily living, it supports tasks such as operating power tools, mowing lawns, lifting up to 30 kg, and working in high-dust environments.

Mechanical Voluntary Closing:
Uses cable-actuated voluntary-closing mechanism with proportional force control through harness tension. Provides real-time proprioceptive feedback for intuitive grip modulation.

Durability and Field-Serviceability:
Resistant to dirt, sawdust, and moisture exposure. Field-serviceable design allows quick maintenance and repair, minimizing downtime for users who rely on their prosthesis for work.

Standard Compatibility:
Integrates with standard body-powered harness systems and common wrist units, making it compatible with existing prosthetic setups without requiring complete system replacement.

L7499 - VCAL Cartridge Justification

The VCAL (Voluntary Closing with Auto-Locking) Cartridge is a proprietary, field-replaceable component that adds integrated auto-locking capability to the ProHensor® VC terminal device.

Auto-Locking Mechanism:
Provides user-controlled locking that maintains grip without continuous cable tension. This feature is medically necessary to:

- Prevent overuse injuries and fatigue from sustained harness loading
- Enhance safety by maintaining secure grip during critical tasks
- Reduce cognitive load, allowing focus on task execution
- Expand functional working envelope by enabling grip maintenance in various arm positions

Three Operational Modes:

- Wide Grip: For handling larger objects or power tools
- Narrow Grip: For precision tasks and smaller objects
- Voluntary-Closing Only Mode: Disengages the locking system for repetitive tasks requiring quick release and dynamic grip modulation

Novel Technology:
The VCAL Cartridge represents functionality not described by any existing HCPCS code. No predicate code exists for:

- Add-on locking mechanisms for voluntary-closing devices
- Three-mode operational capability in mechanical terminal devices
- Field-replaceable locking cartridges that transform device functionality

Field-Serviceable Design:
Can be installed or replaced by prosthetist or informed user, allowing for quick restoration of locking function without full device replacement. Extends device lifespan and supports long-term prosthetic success.

Clinical Benefits:
Designed for users requiring sustained grip capability beyond standard voluntary-closing devices. Addresses known barriers to prosthetic abandonment including fatigue, safety concerns, and functional limitations. Suitable for industrial, trade, and occupational demands where sustained grip, multitasking, and safety are clinical priorities.

Appendix B: Visual Comparison Tables

Terminal Device Types Comparison

Feature	L6722 Device (Standard VC)	Myoelectric Device	ProHensor VC	ProHensor VC + VCAL
Grip Type	Voluntary Closing	Electrically Activated	Voluntary Closing	Voluntary Closing with Locking
Locking Capability	No	Variable, Software Dependent	No	Yes (Auto-Locking)
Force Feedback	Limited	Minimal to None	Proprioceptive Cable Feedback	Proprioceptive Cable Feedback
Operational Modes	Single Mode	Software Controlled	Single Mode	Three Modes (Wide, Narrow, VC-Only)
Durability in Harsh Environments	Moderate	Low	High – Dirt, Vibration, Moisture Tolerant	High – Dirt, Vibration, Moisture Tolerant
Serviceability	Factory Only	Factory or Technician	Field-Serviceable	Field-Serviceable (Including VCAL Replacement)
Power Source	Mechanical (Cable)	Battery/Electronics	Mechanical (Cable)	Mechanical (Cable)
ADL Rating	Light to Medium	Light to Medium	Medium to Heavy	Medium to Heavy
Sustained Grip Capability	Limited (Requires Continuous Tension)	Moderate (Battery Dependent)	Limited (Requires Continuous Tension)	Excellent (Auto-Locking)
Cognitive Load	High (Continuous Attention Required)	Moderate	High (Continuous Attention Required)	Low (Locking Reduces Mental Demand)
Fatigue Prevention	Poor	Moderate	Poor	Excellent (Eliminates Continuous Tension)

ProHensor System Configuration Options

Configuration	HCPCS Code(s)	Best For	Key Advantages	Limitations
ProHensor VC Only	**L6722**	Users requiring heavy-duty VC with proprioceptive feedback; dynamic grip tasks without sustained hold requirements	Established code with good reimbursement; durable mechanical function; field-serviceable	Requires continuous cable tension for sustained grip; may cause fatigue in prolonged use
VCAL Cartridge (Upgrade to Existing VC)	**L7499**	Users who already have ProHensor VC and need to add locking capability	Transforms existing device; cost-effective upgrade; addresses emerging needs	Requires documentation of need for upgrade; **L7499** may require more comprehensive documentation
ProHensor VC + VCAL (Complete System)	**L6722 + L7499**	Active users with occupational demands; sustained grip requirements; risk factors for abandonment	Optimal clinical outcomes; prevents overuse injuries; maximum functional capability; addresses abandonment risk from start	Two separate codes require comprehensive documentation for each; higher initial cost

Appendix C: Functional Activities Table

Clinical Benefits and Functional Applications

Feature	Clinical Benefit	Example ADLs Impacted	Why VCAL Enhances This
Voluntary-Closing with Proprioceptive Feedback (VC)	Intuitive grip force control through cable tension; real-time feedback enables proportional force application	Handling delicate objects like glassware, threading bolts, adjusting tool grip strength, variable force tasks	VCAL adds: Maintains grip after achieving desired force without continuous tension
Auto-Locking Mechanism (VCAL)	Provides sustained grip without continuous effort, reducing fatigue; users can apply force then lock, receiving proprioceptive feedback for controlled initial grasping	Holding and carrying heavy objects, sustained tool use, gripping and securing materials, prolonged manual labor	Eliminates continuous shoulder/back strain; prevents overuse injuries; enables multitasking while maintaining grip
Three Operational Modes: Wide Grip, Narrow Grip, VC-Only (VCAL)	Allows versatility in object handling—wide grip for large objects, narrow grip for precision, VC-only mode for repetitive quick-release tasks	Handling tools of varying sizes, gripping small fasteners, holding steering wheel, sorting objects, lifting varying loads	Single device adapts to multiple task demands; eliminates need for device changes; improves efficiency
Field-Serviceable Locking System (VCAL)	Locking mechanism can be quickly replaced in the field, preventing prolonged work interruptions	Industrial and trade work, jobsite tool use, professions requiring constant prosthesis function	Critical for occupational users who cannot tolerate extended downtime; maintains employment capability
Increased Working Envelope (VCAL)	Maintains grip close to the body while locked, reducing strain on the shoulder and improving efficiency in lifting and carrying	Carrying objects close to the torso, using tools at different heights, holding materials for assembly work, ergonomic positioning	Locking enables grip maintenance in challenging positions without continuous tension; reduces compensatory movements
High-Strength Grip for Heavy-Duty, Vibration Environments (VC + VCAL)	Designed to withstand vibration and sustained high-strength applications; VCAL locking prevents grip failures during vibration	Operating power tools such as drills, hammer drills, chainsaws, jackhammers; handling construction materials; using heavy-duty wrenches	Auto-locking maintains security during vibration when continuous tension might fatigue; enhances safety
Compatible with Existing Body-Powered Harness Systems (VC)	Seamlessly integrates into common prosthetic setups, making it easy to adopt without additional specialized components	Transitioning from a conventional body-powered hook, upgrading from a non-locking device	Reduces fitting complexity and cost; familiar operation for experienced VC users
Durability and Resistance to Dirt, Sawdust, and Moisture (VC + VCAL)	Suitable for environments where debris and moisture would typically affect prosthetic performance	Woodworking, construction, landscaping, farming, handling wet or dusty materials, outdoor labor	Maintains function in real-world work environments; reduces maintenance frequency; supports occupational use
Rated for Medium to Heavy-Duty ADLs (VC + VCAL)	Unlike lighter-duty prosthetic hands, the ProHensor® supports high-force and physically demanding activities	Lifting to 30 kg, shoveling, mowing lawns, using hand and power tools, sustained grasping tasks	VCAL locking enables these activities without cumulative fatigue; prevents injury from sustained heavy use
Reduced Cognitive Load (VCAL)	Users receive grip security feedback initially, then can focus on task completion rather than grip maintenance; reduces mental fatigue	Complex assembly tasks, safety-critical work requiring attention to environment, multitasking scenarios, quality control work	Frees mental resources for task execution, safety monitoring, and decision-making; improves work quality and safety
Enhanced Safety (VCAL)	Auto-locking prevents accidental grip failures during distraction, fatigue, or multitasking	Tool operation in hazardous environments, working at heights, handling dangerous materials, safety-critical occupations	Grip does not fail if user is distracted or fatigued; maintains security during unexpected events; reduces workplace injury risk

Appendix D: Appeal Letter Templates

Appeal Letter Template for Denied L6722 Claim

[Date]

[Insurance Company Name]
[Claims Appeals Department Address]
[City, State ZIP]

Re: Appeal for Denied Claim – HCPCS Code L6722
Patient: [Patient Full Name]
Policy #: [Insurance Policy Number]
Claim #: [Claim Number]
Date of Service: [Date]

To Whom It May Concern:

I am writing to formally appeal the denial of reimbursement for the ProHensor® VC terminal device, a heavy-duty, body-powered, voluntary-closing prosthetic terminal device prescribed to my patient, [Patient Name], an upper-limb amputee.

Denial Reason:
[State the specific reason provided in the denial letter]

Response to Denial:

[Address the specific denial reason. Examples below:]

If denied due to lack of medical necessity:

The ProHensor® VC is medically necessary for this patient based on comprehensive clinical evaluation. My patient is a [occupation] who performs [specific heavy-duty activities] requiring a terminal device rated for industrial use. The heavy-duty rating is clinically essential because:

- Patient performs medium to heavy ADLs including [specific activities]
- Work environment includes [harsh conditions: vibration, dirt, moisture, etc.]
- Standard light-duty devices would fail under these demands
- Proprioceptive feedback is necessary for safe grip control during [specific tasks]
- Field-serviceability is required to minimize work interruption

[Include additional clinical justification specific to patient]

If denied due to insufficient documentation:

Enclosed please find additional documentation supporting medical necessity:

- Enhanced letter of medical necessity with detailed clinical rationale
- Physician prescription clearly indicating heavy-duty voluntary-closing device
- Functional assessment documenting patient's occupational demands
- [Additional documentation as appropriate]

If denied due to PDAC verification:

[If PDAC verified:] The ProHensor® VC has received PDAC verification under code **L6722**. PDAC verification number: [insert number]. Please verify at www.dmepdac.com.

[If PDAC pending:] PDAC verification for the ProHensor® VC is currently in process. Please contact Marins Inc. at Admin@MarinsMed.com for current status. We respectfully request provisional approval pending PDAC completion, or delay of claim processing until verification is obtained.

Clinical Justification Summary:

The ProHensor® VC meets all criteria for HCPCS code **L6722**:

- Heavy-duty rating appropriate for patient's occupational demands
- Mechanical voluntary-closing operation with cable actuation
- Provides proprioceptive feedback essential for patient's functional needs
- Field-serviceable design medically necessary for occupational user
- Durable construction required for patient's work environment

Alternative devices are clinically inappropriate:

- Light-duty VC devices: Insufficient durability for patient's demands
- Myoelectric devices: Not suitable due to [environmental factors, patient needs, etc.]

Patient Impact:

Without appropriate prosthetic device, patient will:

- Be unable to perform occupational duties
- Risk unemployment and loss of independence
- Experience reduced quality of life
- Potentially abandon prosthetic use due to device inadequacy

Attachments:

- Enhanced letter of medical necessity
- Physician prescription
- Functional assessment
- Clinical evaluation notes
- [Additional documentation]
- Itemized invoice

I respectfully request reconsideration of this claim under HCPCS code **L6722** with consideration for the documented clinical need and medical necessity of the ProHensor® VC for this patient. Please contact me if additional information is required.

Sincerely,

[Prosthetist Name, Credentials]
[License Number]
[Clinic Name]
[Phone Number]
[Email Address]

Appeal Letter Template for Denied L7499 Claim

[Date]

[Insurance Company Name]
[Claims Appeals Department Address]
[City, State ZIP]

Re: Appeal for Denied Claim – HCPCS Code L7499 (VCAL Cartridge)
Patient: [Patient Full Name]
Policy #: [Insurance Policy Number]
Claim #: [Claim Number]
Date of Service: [Date]

To Whom It May Concern:

I am writing to formally appeal the denial of reimbursement for the VCAL (Voluntary Closing with Auto-Locking) Cartridge, a prosthetic component that provides auto-locking capability for the ProHensor® terminal device used by my patient, [Patient Name], an upper-limb amputee.

Denial Reason:
[State the specific reason provided in the denial letter]

Response to Denial:

[Address the specific denial reason. Examples below:]

If denied as "not medically necessary" or "not covered benefit":

The VCAL Cartridge is medically necessary as a prosthetic component that provides critical functional capabilities not available in standard voluntary-closing devices. This is not an optional enhancement—it is a medical intervention that prevents predictable complications and enables safe prosthetic function.

Medical Necessity Justification:

1. Prevention of Overuse Injuries (Medical Necessity):
My patient performs [X] hours per day of sustained grip tasks. Standard voluntary-closing devices require continuous cable tension, causing cumulative strain on the shoulder, back, and residual limb. The VCAL auto-locking mechanism eliminates this continuous tension, preventing predictable overuse injuries including:

- Shoulder girdle repetitive strain injuries
- Chronic back pain from compensatory postures
- Residual limb complications from sustained harness pressure

This is preventive medical intervention, not optional convenience.

2. Enhanced Safety (Medical Necessity):
Patient's occupation includes [safety-critical tasks]. The auto-locking mechanism maintains grip during [specific activities] without continuous user effort, preventing accidental drops that could cause workplace injuries. This safety function is medically necessary for [occupational compliance, injury prevention, etc.].

3. Reduced Cognitive Load (Medical Necessity):
Patient's work requires [complex operations, safety attention]. Standard VC devices demand constant mental attention to grip maintenance. VCAL locking allows cognitive focus on work performance, which is essential for [safety, quality, productivity]. This is clinically necessary, not a convenience feature.

4. Expanded Functional Working Envelope (Medical Necessity):
Patient must maintain grip while positioning arm for [ergonomically demanding tasks]. Standard VC devices severely limit this because continuous cable tension restricts positioning. VCAL enables functional positioning that prevents secondary musculoskeletal complications.

If denied as "experimental" or "investigational":

The VCAL Cartridge is not experimental. It is:

- An FDA Class I medical device (Product Code IQZ)
- Based on established mechanical locking principles
- A prosthetic component providing well-documented clinical benefits
- Addressing known problems in prosthetic use (fatigue, abandonment, overuse injuries)

The technology is proven and established. The **L7499** code is used because no existing code describes this specific functionality, not because the technology is experimental.

If denied as "should be bundled with terminal device":

The VCAL Cartridge cannot be bundled with **L6722** because:

- **L6722** explicitly describes voluntary-closing devices without locking mechanisms
- The VCAL adds functionality beyond **L6722** definition
- VCAL is a separate, modular component that can be added to existing devices
- The auto-locking capability is distinct functionality requiring separate coding

L7499 is the appropriate code for prosthetic components not described by existing classifications.

Why No Existing Code Applies:

No current HCPCS code describes:

- Add-on locking mechanisms for voluntary-closing devices
- Three-mode operational capability (wide grip, narrow grip, VC-only)
- Field-replaceable locking cartridges

L7499 ("not otherwise specified") is specifically designed for novel prosthetic components awaiting potential future code assignment.

Clinical Evidence:

Research consistently shows fatigue and discomfort as primary reasons for prosthetic abandonment. The VCAL Cartridge directly addresses these barriers. For this patient:

- [Previous device experience showing fatigue/limitations]
- [Occupational demands requiring sustained grip]
- [Risk factors for prosthetic abandonment]

Patient Impact Without VCAL:

Without the VCAL locking capability, this patient will:

- Develop predictable overuse injuries from continuous cable tension
- Experience cumulative fatigue limiting work capacity
- Face safety risks in occupational setting
- Have high risk of prosthetic abandonment due to functional limitations

Attachments:

- Enhanced letter of medical necessity emphasizing clinical benefits
- Physician prescription with explicit locking capability language
- Functional assessment documenting sustained grip requirements
- Clinical evidence regarding overuse injury prevention
- Safety documentation (if applicable to occupation)
- Comparison showing why standard **L6722** devices are insufficient
- Itemized invoice

Summary:

The VCAL Cartridge provides auto-locking functionality that is:

- Medically necessary to prevent overuse injuries and enhance safety
- Not described by any existing HCPCS code, making **L7499** appropriate
- Clinically essential for this patient's functional needs and long-term success
- A prosthetic component covered under the patient's prosthetic benefits

I respectfully request reconsideration of this claim under HCPCS code **L7499** with full consideration for the documented medical necessity and clinical benefits of the VCAL Cartridge. Please contact me if additional information is required.

Sincerely,

[Prosthetist Name, Credentials]
[License Number]
[Clinic Name]
[Phone Number]
[Email Address]

Contact Information

For questions about products, reimbursement support, PDAC status, or regulatory information:

Marins Inc.
Email: Admin@MarinsMed.com

Additional Resources:

- PDAC Website: https://www.dmepdac.com
- Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database

---

End of ProHensor® Reimbursement Guide

This guide is intended for educational and reference purposes to assist healthcare providers with billing and reimbursement. Final coding and billing decisions remain the responsibility of the provider submitting claims.