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bebionic[®] Reimbursement Guide August 2022



Information for practitioners and payers

Bebionic® Hand Product Information

“The hand is also one of the most important elements of our self-image, second only to the face. Our hands are a tremendous part of how we present ourselves to others. In addition to interacting with the environment in so many functional ways, our hands are a significant part of our psychological and social selves and are a vital element in our sense of feeling whole.” ¹

Multiarticulating/multigrip hands have been shown to provide better function than standard myoelectric hands.^{2,3,4,5} Prosthetists should select multiarticulating/ multigrip hands based on the functional needs of their patients.^{4,5}

A publication from the University of Örebro, Sweden, on a study with the bebionic hand found that patients significantly improved their performance in and satisfaction with ADLs that were important to each patient individually (defined and assessed with the Canadian Occupational Performance Measure [COPM]) at 1, 2, 3, and 6 months after fitting of the bebionic hand. In addition, patients who had reported pain-related disability at baseline experienced a significant reduction in pain-related disability at 3 and 6 months after fitting.⁵

Introduced in 2010, the bebionic offers 14 grip patterns that the user can select from, allowing the amputee to participate in activities that non-amputees take for granted.

- Tasks related to feeding oneself such as buttering toast, cutting food with a knife, carrying a plate of food, and opening jars.
- Carrying bagged items such as groceries, packages, or a laptop case and still have a hand free to open the door.
- Using a key to open the door.
- Performing household chores such as folding laundry, hanging clothes in the closet, sweeping, putting away dishes, etc.
- Light home maintenance and home renovation.
- Office tasks such as writing with a pen, operating a computer mouse and keyboard, or turning a page in a book.

FDA Status

Under FDA’s regulations, the bebionic hand is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device’s safety and effectiveness; therefore, safety and effectiveness research is not required for this device. The bebionic hand has met all applicable General Control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part 820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The bebionic hand is listed under External Limb Prosthetic Component; Product Code IQZ; Listing Number A448082.

Health Canada Compliance

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

Who can provide a bebionic?

The bebionic is prescribed by a physician and may only be provided by a qualified Prosthetist that has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person and online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

Warranty

A 2-year standard manufacturer warranty is provided for the bebionic hand. Repair costs are covered except for those associated with damages resulting from improper use. Service inspections (maintenance) are recommended at 24-month intervals, but not mandatory. The 2-year standard warranty can be extended to 3 or 5 years for a fee, and service inspections (maintenance) are included.

Bebionic® Hand Product Information

Bebionic Wrist Options

- 8E70=* bebionic hand with quick disconnect wrist
- 8E71=* bebionic hand with short wrist (for Transcarpal amputation or long residual limb)
- 8E72=* bebionic hand with flexion wrist and quick disconnect

5Bebionic Coding (U.S. only)



The bebionic is PDAC verified and following codes apply:

- L6880 Myoelectric hand with articulating digits (8E70/8E71/8E72)
- L6621 Flexion/extension wrist (8E72)

Additional components that might be included on a claim for prosthesis with bebionic Hand.

- L6629 Lamination collar with coupling used for quick disconnect for terminal device interchange (8E70/8E72)
- L6026-L6975 External powered base code
- L6883-L6885 Replacement socket code
- L6880-L6884 Test sockets
- L7400-L7405 Socket Material: ultralight/acrylic

Suspension

- L6686 • Suction
- L6687-L6690 • Frame
- L6691-L6697 • Inserts/Liners

Above Elbow Additions:

- L6693 • Forearm counterbalance
- L6637 • Electric lock
- L7181/L7181 • Microprocessor control (sequential/simultaneous)
- L7259 Electric wrist rotator
- L7009 Additional Terminal Devices: Greifer
- L6646 Shoulder Unit
Harness (L6672 / L6677/ L6655 + L6677)

- L6811 Additional Switches or Linear Transducer
- L6890 Glove
- L7600 Prosthetic Donning Sheath
- ⁶L7499 Pattern Recognition

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- ¹ Smith DG. Introduction to upper-limb prosthetics: Part 1. 2007 March/April;17(2):40-44
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- ⁴ Kannenberg A, Lundstrom R, Hibler KD, Swanson Johnson S. Differences in two multi-articulating myoelectric hands for facilitating activities of daily living in individuals with transradial amputation: A cross-sectional study. J Prosthet Orthot: January 16, 2022; Online first publication, doi: 10.1097/JPO.0000000000000411
- ⁵ Widehammar C, Hiyoshi A, Lidstrom Holmqvist K, Lindner H, Hermansson L. Effect of multi-grip myoelectric prosthetic hands on daily activities. J Rehabil Med 2022; 54: jrm00245, doi: 10.2340/jrm.v53.807
- ⁶ The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alphanumeric system changes.
- ⁷ It is not recommended to bill L7499 to Medicare for the Myo Plus pattern recognition at this time.

bebionic® Features and Benefits

Proportional Control: The bebionic's proportional speed and grip force provides precision control when performing delicate tasks, allowing the user to do things like pick up an egg or hold a polystyrene cup.

Automatic Grasp Feature: Its auto grip feature means no more accidents, as bebionic automatically senses when a gripped item is slipping and adjusts the grip to secure it. The bebionic's multifunctional design and advanced materials makes it strong enough to handle up to 45kg – so the user can confidently use the hand to carry heavy objects, and push up from a seated position. Soft finger pads and a wide thumb profile maximize the surface area and enhances grip.

The mobility of multiple fingers is very important to patients, and not just for emotional reasons. The needs and requirements of people who rely on a prosthetic arm have changed; especially in the increasingly digital working world and recreational environment. Bebionic is a commercial prosthetic hand designed to enable amputees to perform everyday activities, such as eating, drinking, writing, typing, turning a key in a lock and picking up small objects. Bebionic is comfortable, precise and intuitive for patients, transforming the lives and abilities of amputees around the world – from helping them perform simple tasks like tying shoelaces to giving them back their control and their pride.

The bebionic includes 14 selectable grip patterns and hand positions which enable the user to perform many everyday activities with ease.

1. **Active Index grip** enables the user to effectively operate home and garden appliances with trigger mechanisms, like handheld sprays, hairdryers and power tools. With active index grip, the user's hand grips the object, while maintaining control over the index finger to operate the trigger. The active index grip is the ideal hand position for using a keyboard. Objects are grasped and held with the thumb, middle, ring and little fingers, and the index finger subsequently bends. The user can then control and position the index finger independently.



bebionic® Features and Benefits

2. **Column grip** allows the user to operate levers and firmly press buttons. The column grip can be used when driving, to use car indicators, at work to operate elevator buttons, or at home to switch on appliances or button a jacket. The user can push objects or operate larger buttons and switches with this grip. We also recommend using it when dressing since the thumb will not get caught in clothing as easily. With the column grip, the thumb is moved from the lateral position towards the palm. The fingers then close over the thumb, making a sort of fist.
3. **Finger Adduction grip** is great for picking up and holding thin objects. When eating, the grip can be used to hold cutlery or it can be used when brushing teeth. Finger adduction can also be used to pick up papers, leaflets and magazines. The fingers of the bebionic hand move together naturally as they close. This allows the user to more securely grip thin objects, such as cutlery or magazines, between the fingers for a uniquely confident grasp. Finger adduction performs especially well with the hand closed. It can also be used together with the key grip and pinch grip.
4. **Finger Point grip** allows the user to perform tasks like pressing small or intricate buttons, such as a doorbell. When using a computer finger point allows the user to operate the keyboard and touch screen. The hand can be moved to the finger point position when the thumb is in the lateral position. The middle, ring and little fingers close against the palm and the thumb moves against the middle finger.



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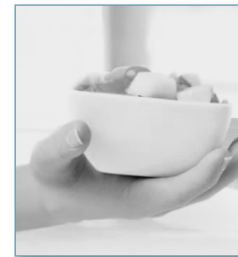
5. **Key grip** is ideal for reading a magazine, using a spoon or for holding a thin, flat object such as a plate, a credit card or a key. It provides precise, accurate control, and enables the user to complete intricate tasks such as unlocking a door, folding a towel, or carrying a tray. The fingers close part way when the thumb is in the lateral position. The thumb then closes onto the side of the index finger. The user can then raise and lower the thumb position without moving the other four fingers. This allows for easy release, hold, or reposition of the object being gripped.



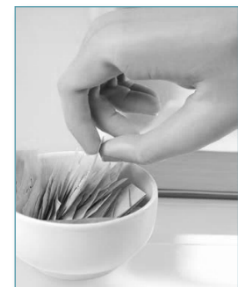
6. **Mouse Grip** Whether working in the office, browsing the internet, or playing video games at home, the mouse grip is ideal. The mouse grip lets the user operate a computer mouse. The thumb and little finger close to hold the sides of the mouse, with the middle and ring fingers providing additional stability. The index finger closes on to the mouse button and then backs off to provide the button press. The user can achieve a mouse click with a close signal to the hand and release the mouse with an open signal.



7. **Open palm grip** provides an effective way of carrying bowls or plates naturally and safely in the palm of the Bebionic hand. The user can fully open the hand to provide a flat palm when the thumb is in the lateral position.



8. **Pinch grip** allows the thumb and index finger come together to provide a versatile, useful way to pick up and maneuver a wide range of small objects, including car keys, coins, lids and pens. The pinch grip is particularly suitable for manipulating objects precisely.



bebionic® Features and Benefits

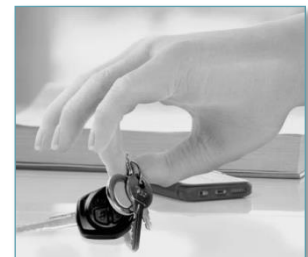
9. **Flexible Power grip** provides just the right amount of grip to suit any situation, whether shaking someone's hand, throwing a ball, using home and garden utensils or eating a piece of fruit. This grip pattern enables the user to hold round or cylindrical objects more easily and, above all, more securely.



10. **Precision Closed grip** provides a quick, reliable method of picking up and moving small, objects such as a coin or tissue. With precision closed grip, the index finger grips against the thumb while the rest of the fingers close onto the palm. This grip is similar to the precision open grip, but is particularly suitable for situations where extended fingers would get in the way – for instance when working at a desk. The middle, ring and little fingers are bent first and close into the palm; the thumb then moves to the midpoint of its movement range and pauses there. After that, the user has full control of the active index grip.



11. **Precision open grip** offers another useful way to pick up and manipulate small objects quickly and accurately. With precision open grip, the index finger grips against the thumb while the middle, ring and little fingers remain open. With precision open grip, the user can pick up and manipulate small objects with the thumb in opposition. Two activities the user would learn to do with this grip is open a candy bar wrapper and close a zipper. The index finger meets the static thumb in this case. When a close signal is applied, the thumb moves to the midpoint of its range and pauses there. The index finger is then active and under the user's control while the middle, ring and little fingers remain extended.



12. **Relaxed hand position** helps to give a natural and lifelike appearance. In the relaxed hand position, the thumb is positioned slightly towards the palm in the lateral position. The other fingers are slightly bent. By applying a further signal, the hand is moved into the hook grip for carrying objects.



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13. **Tripod grip** is used to pick up, hold and manipulate a variety of everyday objects including car keys, coins, jar lids and pens. This grip can be used tie shoe laces and to open/lift a lid. As soon as the thumb is in opposition, the user can close the hand in the tripod grip so the thumb, index and middle fingers meet. The ring and little fingers close.



14. **Hook grip** provides the perfect solution. Secure and versatile, hook grip enables the user to carry everything from briefcases and handbags to heavy shopping bags.



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