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Expert Consult:

Prosthetic Criteria and Considerations for Life Care Planning

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Providing for prosthetics in a life care plan, Life Care Planners commonly use clinical care procedures and prices from the billing record. Unfortunately, although this sounds logical and reasonable, using past prosthetic services and invoice history can and often will be indefensible for future prosthetic cost, design and replacement cycle. In part, this is because the timeline and deadline to provide an accurate life care plan may not be compatible with the patient having reached maximum medical improvement (Meier, Choppa, and Johnson, 2013).

Projecting future costs related to the prosthesis can be predicted accurately. However, this requires integrating prosthetic assessment history with clinical practice guidelines, standards of care, current and potential functional level assessment while applying fair market value of current technologies.

Prosthetic Rehabilitation

The primary challenge is that life care plans are commonly produced within 1-3 years of the initial injury. But patient treatment process, needs, and requirements for an individual vary considerably between post-surgical rehabilitative intervention (Esquinazi, 2004) and long-term services: prosthetic care and related expenses for the first 18-36 months (early care) after amputation are significantly different compared to long term prosthetic care. Understanding the differences between the clinical care and billing records is key.

The 3 primary differences between early rehabilitation and lifetime care are

1. Rehabilitative care vs. long-term care

2. Contract pricing vs. fair market value

3. Benefits coverage vs. medically necessary care

Rehabilitative care vs. long term care

Immediately following amputation, the patient is understandably faced with a life changing transition. Aside from the emotional, psychological and social challenges of missing a limb, there are some very specific physiological issues that must be clinically addressed when providing a prosthesis (Ulger et al., 2018). Post-surgical physical conditions create specific and unique clinical and billing occurrences during early rehabilitation that should not be continued in long term care.

The primary post-surgical issue for prosthetic fitting is significant post-surgical edema. This increases the size and shape of the residual limb. Although compression therapy will help over time, a significant contributor to edema reduction is movement and exercise to stimulate vascular and lymphatic return. This can be achieved by wearing a prosthesis.

The patient's residual limb will be sensitive, muscles and joints are painful, and the patient will need to learn how to walk with a prosthetic device. One clinical option for early rehabilitation is to provide an Immediate Post-Operative Prosthesis, or IPOP to allow for early ambulation and rehabilitation; this also contributes to vascular return and edema reduction (Samuelson, Andrews, and Hauddek, 2017). This style of prosthesis is specifically intended for immediate post-surgical care, and its costs and services should not be duplicated for long term care.

The next rehabilitation stage may include a preparatory prosthesis, somewhat self-explanatory. Its purpose is to prepare the residual limb for full weight bearing, reduce post-surgical edema, and provide a basic prosthetic design to enable the patient to learn to walk (for the lower limb amputee) or use a hand or terminal device (for the upper extremity amputee).

Wearing a preparatory prosthesis will predictably decrease residual limb edema to the point where the socket will no longer fit properly, requiring replacement. A replacement socket can be custom designed and attached to the existing components, effectively providing what may seem like a new prosthesis. Although replacement sockets are used for long term care and should be included in a life care plan, replacement frequency in early rehabilitation is much higher than in long term care.

The socket replacement cycle during post-surgical care is very short: in initial rehabilitation the socket may need to be replaced as frequently as once every 3-6 months. However, once the residual limb has fully matured, with the post-surgical edema expelled and the muscles atrophied, a prosthetic socket has a normal life span of up to 24-30 months.

FIGURE 1 - Reasonable replacement times for components in amputation rehabiltation.

	IPOP	Preparatory	Socket Replacment	Definitive Prosthesis
Device				
Fair Market Value (FMV)	$4,959	$15,616	$ 12,318	$40,583
Reasonable Useful Life (RUL)	1-2 Months	6-18 Months	6-30 Months	5 years

Both the preparatory prosthesis and IPOP are very simple in design and meant for short term use. Costs related to prosthetic devices used during rehabilitation are typically less than prosthesis designed for long term wear. (Figure 1) Therefore, any costs related to IPOP, preparatory prosthesis, or high frequency of replacement sockets are not relevant to long term cost projections.

Contract pricing vs. fair market value

Discount and contract rates heavily influence the prosthetic industry. There are three major pricing profiles: Medicare, contract, and fair market value. The price of any style prosthesis can vary significantly depending on patient location and payor source.

Clinical care and billing records can have a significant effect on the price of the prosthesis depending upon insurance benefits or network: for example, pricing of the same transtibial prosthesis can vary by over $8,200. (Figure 2)

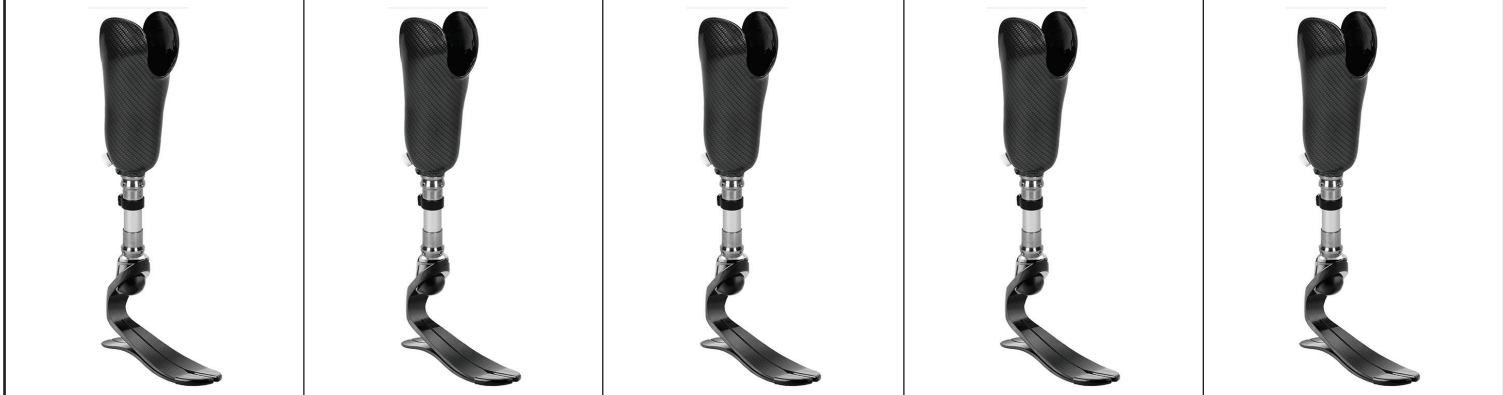
The ultimate determinant is the industry standard, the L-Code system. The Center for Medicare and Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) identifies each prosthetic element with a specific four-digit L-Code; each code has a specific reimbursement. Medicare provides a sustainable, fair, and reasonable reimbursement in the United States, because on average, 50% of prosthetic industry patient volume and revenue base consists of patients who are Medicare beneficiaries (Hanger Clinic, 2017).

This matters because each prosthetic provider entity is owned and operated by either a private or public corporation. Antitrust regulations prevent companies from setting or fixing price levels as a group or industry, so each prosthetic provider must establish line item pricing for each code, commonly referred to as usual and customary (U&C), manufacturer suggested retail price (MSRP) or fair market value (FMV), based upon personal preference, experience and competitive market conditions. The fair market value for prosthetic providers is commonly set between 20% to 30% above Medicare pricing.

Each L-Code can have up to twelve different reimbursement levels depending upon the service location. The lowest reimbursement level is referred to as the Medicare floor; the highest, the Medicare ceiling.

For example, the 2019 Medicare reimbursement for the microprocessor L5973 foot has a floor to ceiling variance of $2,317.53 based solely upon where the patient receives the care: (Figure 3). Therefore, the expected fair market value consumer price for this will be between $20,728 (20% > Medicare average reimbursement) to $22,793.90 (30% > Medicare average reimbursement).

FIGURE 2 - Pricing variations depending on payor source.



Private Insurance In Network Pricing	Medicare Floor	Medicare Average	Medicare Ceiling	Fair Market Value
$11,824.68	$13,911.39	$17,391.83	$20,872.26	$21,913.70

The NLCP should closely evaluate any invoice history for prosthetics to the determine the level of contract discounting applied. Failure to do so can have a negative impact on future plan projections.

Benefits coverage vs. medically necessary care

While insurance and other collateral sources are not considerations in most life care planning cost projections, it's useful to understand the significant role insurance has in treatment decisions and billing history. An individual may select an economical insurance plan with limited or no

FIGURE 3 - Medicare pricing variations by states/territories.

Location	Medicare Reimbursement	L5973 Microprocessor Foot
NJ, NY (Floor)	$16,898.67	
DC, DE, MD, PA, VA, WV	$16,999.17	
CT, MA, ME, NH, RI, VT	$17,035.47	
AK, HI	$17,051.77	
AZ, CA, ID, NV, OR, WA	$17,069.18	
AR, LA, NM, OK, TX	$17,206.77	
AL, FL, GA, KY, MS, NC, SC, TN	$17,208.35	
IA, KS, MO, NE	$17,402.53	
CO, MT, ND, SD, UT, WY	$17,540.94	
IL, IN, MI, MN, OH, WI	$17,563.51	
VI	$18,634.42	
PR (Ceiling)	$19,216.19	
Medicare Average	**$17,288.90**	**Average FMV = $21,784.02** (26% above Medicare Average)

There are three major pricing profiles: Medicare, contract, and fair market value. The price of any style prosthesis can vary significantly depending on patient location and payor source.

coverage for prosthetics, which is reasonable considering that traumatic amputation is obviously unforeseeable. However, once the amputation has occurred, the patient is now challenged with limited benefits with access to only basic or restricted care options.

An individual with amputation of the arm above the elbow may meet all medically necessary criteria for an advanced myoelectric prosthesis. However, if the insurance policy at the time of the accident only covers basic services, the benefit will provide only for a body-powered prosthesis with harness and hook. Past billing and clinical care history for this patient would indicate a prosthesis with a fair market value of $17,000, consistent with what the patient's benefit coverage at the time.

However, that cost projection using only past billing and history would result in a gross underestimation, because medical records and supporting documentation could establish and validate that medically appropriate and necessary care would be a myoelectric prosthesis with a fair market value of $76,000 per device. (Figure 4)

Two individuals of the same age with identical insurance benefits from one insurance company could have different coverage based upon the cause of amputation. The Aetna medical policy states that a microprocessor knee can be medically necessary when the amputation is "from a non-vascular cause" (Aetna, 2019).

Therefore, a life care plan for Patient "A" with limb loss caused by a motor vehicle accident would be covered for a microprocessor knee. Patient "B" whose limb loss was related to vascular surgical malpractice would not.

These two very similar cases reveal why reviewing their past medical files and billing should logically be the same but are not. Prostheses for these two patients with the exact same insurance policy and exact same amputation level would look similar to the untrained eye, and both provide the same basic function is so much that they both enable the patient

FIGURE 4 - FMV (past billing) vs. medical necessity for arm prosthetic, representative example.

Basic Body Powered Prosthesis with suspension harness and hook	Self-Suspending Myoelectric Prosthesis with Bionic Hand
	
$17,765 Fair Market Value	**$76,430 Fair Market Value**

It is critical for the NLCP to recognize limited service options due to benefit coverage restrictions for past care; these collateral sources must not apply to life care plan projections for medically necessary and appropriate future care.

to walk. But the two prosthesis contain very different knee components.

Patient "A" invoice history would include an advanced microprocessor computerized knee that provides optimum stability at a value of $42,385 per prosthesis, while Patient "B" invoice history would have a basic mechanical knee at a value of only $17,456 per prosthesis. (Figure 5)

Be aware that past clinical care and billing history can be heavily influenced by insurance contract limitations and policy language which can limit access to medically necessary and reasonable technologies during rehabilitation. It is critical for the NLCP to recognize limited service options due to benefit coverage restrictions for past care; these collateral sources must not apply to life care plan projections for medically necessary and appropriate future care.

Functional level

Prosthesis style, model, and type decisions are primarily based on potential functional abilities as measured by the industry standard Functional K Level. This validates medical necessity and directly affects cost (Table 1).

Prosthetic services and components are considered reasonable and necessary, according to Social Security Act § 1862(a)(1)(A) provisions. For an individual with a lower limb amputation, prosthetic devices are determined medically necessary when a qualified health care professional evaluates and documents that an individual "will reach or maintain a defined functional state within a reasonable period of time and is motivated to ambulate" (CMS, n.d.).

Potential functional ability is based on the prosthetist's and treating physician's reasonable expectations, considering factors including, but not limited to the individual's past-history (including prior prosthetic use if applicable), current condition: status of the residual limb and the nature of other medical problems combined with the individual's desire to walk.

Functional level validates the best possible activity level of the prosthetic wearer, and the technology needed to achieve optimal functional level in activities of daily living. The cost of technology is directly proportional to functional level.

For a prosthetic foot, the fair market value for a K1 foot ranges from $304 to $415; a K2 foot component ranges from

$304 to $543. A person who can use a K3 foot is looking at a much wider range, $961 to $22,752 for just the foot component. For prosthetic knees the range is even greater: a simple functional K1 knee can cost as little as $448 and a functional level K3/K4 waterproof microprocessor knee component has a fair market value of over $70,000.

An individual's functional level is a key factor in planning, especially if the mechanism of injury for the amputation caused other injuries and co-morbidities that might negatively impact the functional K Level. It is not uncommon for an individual to be classified as K1 or K2 for the first post-injury year to eventually progress to functional level K3 or K4 over time. When preparing a life care plan for an individual with a lower limb amputation, past, present and future functional K Level must be taken into consideration to ensure an appropriate and accurate projection. There are no functional standards or restrictions for individuals with an upper limb amputation.

FIGURE 5 - Different allowed benefit by cause of limb loss, representative example.

		
Patient	A	B
Insurance	Aetna	Aetna
Cause of Amputation	Trauma	Vascular
Prosthetic Benefit	Microprocessor Knee	Mechanical Hydraulic Knee
Fair Market Value	$68,447	$36,716

Activities and prostheses

The primary function of a prosthesis to provide comfort and function and enable the individual to accomplish expected activities of daily living (ADL) that match the individual's functional K Level. An ADL prosthesis has components and technology for features enabling the wearer to access a community environment consistent with functional level and day-to-day routine tasks.

An ADL prosthesis may not be able to accommodate appropriate function, durability, comfort, or cosmetics for functional K3 or K4 (and select K2) individuals. These individuals need will meet medical necessity for activity prosthesis. Evidence based clinical practice guidelines (VA and DOD, 2008 and 2017) identify the clinical efficacy of specialized prosthetic limbs that are "specifically focused on certain functional tasks" (VA, DOD, n.d.).

Specialty prostheses enable participation in vocational, social or personal activities that would be restricted with the limitations of the ADL. The NLCP should assess whether the individual has work, recreational, or specialized activities that require specialized or unique design features.

It would be uncommon for an activity prosthesis to appear in the record while the residual limb is undergoing stabilization and the individual is still in the rehabilitation phase. After 36 months, few if any prosthetic wearers will have a history of owning an activity prosthesis, largely because most insurance carriers only provide benefits for one prosthesis at a time. Although the patient may not have had a special activity prosthesis in the past, the NLCP should consider providing for one in the plan based upon functional level, avocational activities, and lifestyle.

Reasonable useful life

A prosthesis (CFR, 414.202) is classified by Medicare as durable medical equipment prosthetics orthotics and supplies (DMEPOS) (CFR 424.57). Government regulatory standards for the replacement of a prosthetic device stipulate that a prosthesis that has been in continuous use (CFR, 414.230) has a reasonable useful lifetime (RUL) of no less than 5 years (CFR, 414.210)

The "no less than 5-year" time frame for lower limb prosthesis is supported by peer reviewed published studies. A retrospective study (Narang, 1982) of 14,400 prosthetic wearers over a 25-year time period established the average life of a prosthesis is about 5 years. Although this large study is over 40 years old, a smaller 1992 clinical study (Nair, 2008) following 173 lower limb prosthetic wearers over a 10-year period indicated that transfemoral amputees in this study on an average needed one new prosthesis every 10 years while transtibial amputees needed a new prosthesis every 7 years. A more current study (O'Keeffe, 2019) determined that prostheses may last for 5 to 7 years with intermittent requirement for consumables replacement, e.g., socks, straps, and liners.

Reasonable useful life of a prosthesis can be negatively affected by, but not limited to the following: (Local Coverage Articles, n.d.):

- A change in the physiological condition of the patient
- Irreparable wear of the device or a part of the device
- The condition of the device, or if part of the device requires repairs and the cost of such repairs would be more than 60% of the cost of a replacement device, or of the part being replaced.

When calculating the average reasonable useful life of prosthesis over a patient's lifetime, it is appropriate to use a replacement cycle of 5 years (Hachisuka, Nakamura, et al., 2001) while realizing that extenuating circumstances can reduce or extend the life of a specific prosthesis.

Due to normal and expected changes in the residual limb, the prosthetic socket may lose appropriate fit and function making the prosthesis unusable, even though the prosthetic components (knee, foot, ankle) are still functional and appropriate. In this event the prosthetic socket can be replaced and secured to the existing functional prosthetic

components. Included with the replacement socket are the required consumable items (e.g., liners, socks) and required maintenance to the components. It is reasonable to include a replacement socket at the half-life of the prosthesis to accommodate physiological change in the size and shape of the residual limb.

Supplies and maintenance

There are predictable supplies and maintenance for a prosthesis wearer. With the most common prosthetic designs, liners and socks worn next to the skin over an extended period can cause hygiene issues related to sweat and bacteria (Hachisuka, Nakamura, et al., 2001), requiring annual replacement.

A common. shortcut approach to calculate supplies and maintenance is to apply a yearly amount based upon a percentage of the total cost of the prosthesis (MacKenzie, Jones, Bosse, et al., 2007). But there is no clinical, scientific, medical or published peer reviewed evidence to support or validate this for any configuration of user, equipment, K level, or supply quality.

Supplies and maintenance can be estimated accurately for key prosthetic elements. Consumable items and their life cycle can be clearly identified and priced. Most prosthetic components have a full manufacturer's warranty up to 3 years with some up to 5 years, during which time allowance for replacement is not reasonable. It is reasonable to include a 2-3 hours of clinical support for maintenance and follow-up for miscellaneous services and care.

There is no need for supplies and maintenance expense for the years that a new prosthesis or replacement socket are being provided, as the prosthesis and replacement socket includes liners, socks, maintenance and follow-up care.

A 5-year cycle for a prosthesis will therefore include one (1) Prosthesis, one (1) Replacement Socket and three (3) incidents for Supplies and Maintenance (Figure 6)

Conclusion

In a life care plan for an individual that has undergone an amputation, prosthesis costs will often be a significant, if not the largest, line item. Although historical and current prosthetic records contain valuable information to establish the style, type, and cost of prosthesis the patient has had in the past or is currently wearing, these records cannot be solely relied upon to produce accurate future cost projections.

They do, however, provide the basis to create an accurate and defendable long-term prediction of prosthetic costs: historical information. This provides the foundation to corroborate functional level to establish appropriate and medically necessary care and technology. Past billing records can however, be useful to help identify specific HCPCS L-codes; this will assist in calculating current fair market value. The NLCP must consider key factors related to current prosthetic clinical practice guidelines, coding, billing practices, and regulatory standards to develop a life care plan for an individual suffering from limb loss.

FIGURE 6 - 5-year cycle for replacement items, representative example.

New Prosthesis	Supplies & Maintenance	Supplies & Maintenance	Replacement Socket	Supplies & Maintenance	New Prosthesis
2020	2021	2022	2023	2024	2025

TABLE 1. Functional ambulation levels (K-Levels)

K0 Level 0	Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
K1 Level 1	Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
K2 Level 2	Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
K3 Level 3	Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
K4 Level 4	Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Sources: Centers for Medicare & Medicaid Services, Local Coverage Determination (LCD): Lower Limb Prostheses (L33787) United Health Care, Prosthetic Devices, Specialized, Microprocessor Or Myoelectric Limbs, Guideline Number CS104.I, Effective Date December 1, 2018

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