

Prescription Criteria for Prosthetic Provision for Lower Limb Amputees - Full Clinical Guideline

Reference no.: CG-T/2024/113

1.0 Introduction

- 1.1 Prosthetics prescription guidance: provides a basic framework for specialised prosthetic limbs that are available.
Generally the Prosthetist is responsible for the prescription and can involve MDT and/or Peer Review as appropriate.
The guidance outlined is an evolving process, due to advances in technology.
- 1.2 Prosthesis definition: for upper and lower limb amputees:
Prostheses are sophisticated medical devices that replace the form and function of absent limbs. Prostheses are designed to rehabilitate each individual for their normal activities of daily living and return to their pre-amputation activities wherever possible.
Prostheses and parts used are single use and patient specific.
- 1.3 In some exceptional cases, deviation from the guidance is possible.
An MDT assessment may be required to establish potential functional outcomes which may improve with an enhanced new prescription.
Outcome measures can assist in this process.
External funding may also be appropriate (see 9.3)
- 1.4 Ultimately the prescription responsibility lies with the Prosthetist, balancing clinical need, comfort, function, cosmesis and value/cost considerations

2.0 Additional Prostheses

2.1 Indications for prescription of additional lower limb prosthesis

- 2.1.1 A single prosthesis may not fulfil all the functional requirements of an individual user, in one prescription.
A separate prosthesis may be required to achieve certain functions or for certain circumstances.
- 2.1.2 Additional limbs can be provided, as appropriate, depending on clinical need and prescription criteria: see **2.2**
- 2.1.3 A secondary prosthesis should be of a suitable prescription and function depending on clinical need. However it may not necessarily be an exact duplicate, especially for high cost components: e.g. microprocessor knees and some high cost feet.

2.2 The prosthetic user must meet 3 of the requirements as identified below:

- 1 In full/part time employment.
- 2 Full/part time education.
- 3 Full/part time carer e.g. young children (parent) or dependant.
- 4 Growing child.
- 5 A or K code: A2L (K2) or higher.
- 6 Prosthesis is for a specialist function.
- 7 Change in specification or prescription.
- 8 Wears prosthesis more than 8 hours a day to mobilise or function.
- 9 Not possible to change sockets or repair prosthesis on the same day.
- 10 Has fluctuating stump volume.
- 11 Complex fitting and/or alignment (e.g. vulnerable skin/short residuum).
- 12 High activity and/or weight resulting in frequent major repairs.

2.3 If not meeting the eligibility criteria

Consider maintaining with 1x prosthesis, if clinically appropriate.
This may result in extended time spent at the centre (>2hrs), when a new socket and/or major repairs are required

2.4 Prescription/Specification changes

Normally the replaced limb would be assigned for disposal.
However this prosthesis could potentially be re-purposed, if appropriate and retained by the patient.
For example: for use as a specific function eg cycling, fishing or other activities as agreed on an individual basis.

3.0 Water Activity (Waterproof) Prostheses

3.1 Indications for prescription of Water Activity Limbs

Generally prostheses are not considered waterproof and have components which can corrode and fail, if subjected to repeated immersion.
Prosthetist will identify with the user, if a waterproof prosthesis may be appropriate

3.1.1 Normal Activity of Daily Living

Some prostheses are specific for showering. Prescription of these will be considered case by case via an MDT assessment
Prosthetic users who have access to a wet room and/or have significant modifications at home will not be routinely considered for a shower limb.

3.1.2 Activities which may require prescription of a waterproof prosthesis

Occupational: Fishing, Diving, Wet environments (wading or high humidity environments).

Leisure: Access to swimming, Fishing, Sailing, Kayaking, any access to water.

3.1.3 A specific waterproof prosthesis may be issued to reduce long term cost: reducing the probability of frequent repairs and replacements, for example if the user is incontinent

3.1.4 Minimum activity requirement for safe use: the individual must have potential to achieve SIGAM Db (A2L: K2: see Appendix 2). The frequency of use will also be considered: as would not be appropriate purely for holiday use.

3.1.5 In some circumstances a waterproof prosthesis may be considered and agreed with Peer and/or MDT review

3.2 One piece laminated prostheses

Manufacture is very time consuming, therefore modern modular waterproof prostheses are now favoured.

3.3 Modular waterproof prostheses

Modular WAL has a higher cost for components (compared to 3.2) but is able to utilise a standard build for the socket

As such reduces the need to remake the whole prosthesis every time a new socket interface is necessary

4.0 Sports Prosthesis

4.1 Indications for prescription of Sports specific prosthesis

4.1.1 Sports specific prostheses are not normally prescribed on the NHS. Sport prostheses are designed to improve performance in a particular specific sport.

Note: the sport components are not usually outside of normal funding levels; however, the time to set up correctly can be prohibitive.

4.1.2 In some circumstances it may be possible to fund sport prosthesis via external funding via:

Veteran's Prosthetic Panel

Commissioner: Individual Funding Request.

These applications often require an application, assessment, and do not guarantee funding.

5.0 High activity and Multiple function Prostheses

5.1 High Activity prostheses are provided on the NHS depending upon: individual case, activity scores, outcome measures and clinical need. This type of prosthesis will often be multiple function: including use for occasional sport if required.

5.1.1 High body weight (>100kg) and activity level: exert high cyclical loading to the prosthesis, even during relatively sedentary activities. Some specialist or sport components may be prescribed if appropriate.

5.2 Multiple function high activity prostheses are appropriate for everyday use and can also be used for other activities.

This type of prosthesis is appropriate where normal activities of daily living exert high impact and/or cyclical loading, above normal ambulation parameters:

Leisure:

Running, Jogging, regular Gym use, Badminton, Horse riding, Football, Cycling, Golf.

Occupational:

Farmer, Security guard, Fitness instructor, Building, other occupations which require either high impact cyclical loading or handling of heavy loads.

Note: the above lists are not exhaustive

6.0 Silicone, Polyurethane, Gel liners: Compression socks and Stump Socks

6.1 Indications for prescription of Silicone Polyurethane and other socket liners Locking/Cushion/Suction types

6.1.1 Silicone, Polyurethane and Gel liners will be prescribed where clinically appropriate for some of the following indications:

Skin grafts and scar tissue

Bony prominences

Suspension

Protection from abrasion and skin traction

6.1.2 As these are relatively high cost (interface) items (£200 - £500): one will be issued and replaced once the Prosthetist agrees necessary. Normally one Locking/Cushion/Suction liner will be issued at a time.

The user must bring the liner in for inspection prior to a new one being ordered.

If the liner fails within the warranty period it must be returned to the manufacturer.

6.1.3 If a user requires multiple liners annually (>3): a Review appointment will be required to reassess the prescription to consider appropriateness and possible alternatives.

6.1.4 Contraindications for use of Silicone, Polyurethane and Gel liners

Poor manual dexterity

Poor cognitive ability

Poor hygiene

Distal hypersensitivity

Unable to tolerate total contact socket

6.2 Stump socks and Gel socks

6.2.1 Indication: to provide an interface between the prosthesis and skin. Help to reduce friction, provide padding/protection and wick moisture

6.2.2 Cotton, Wool, Mixed fibre socks

The most common types of socks used as an interface and require regular laundering.

The maximum number of 10 issued in a year for normal use. If exceeding 10 annually a Review will be required to ensure optimal fit of the prosthesis and consider alternatives if appropriate

The number of socks required annually will be agreed by the Prosthetist depending on activity, wear and other clinically appropriate factors.

6.2.3 Indications for Gel socks and protectors:

Protection of vulnerable skin, scars, skin grafts.
Improving condition of scar and graft tissue (moisturise)
Reduce and/or absorb shear pressures from the socket interface

6.2.4 Silicone, Silicon and Mineral Gel

Dermaseal, Silipos or other types of Gel socks and protectors are issued where clinically appropriate. Normally one issued at a time and replaced when worn.

These are lower cost (£30 - £50) protection (compared to 5.1). A maximum of 4 issued annually. If this issue is exceeded a Review is required to consider alternative prescriptions if appropriate.

It may be more cost effective to consider Cushion liners (5.1) with a greater longevity.

6.3 Compression socks (Juzo type)

6.3.1 Indications: for use post-surgery to control oedema prior to prosthetic rehabilitation: (see Appendix 3)

6.3.2 Normally one Compression sock will be issued in the early stages of rehabilitation, prior to receiving a prosthesis.

It may be necessary to replace it with a smaller size if clinically appropriate. When using the prosthesis it will not normally be necessary to have any further compression socks issued unless clinically appropriate

6.3.3 Bespoke Compression socks

Some residual limbs are outside of the normal size chart and may require a bespoke solution when clinically appropriate.

6.3.4 Contra-indications for use of Compression socks:

Stitches, staples and/or drain tubes still in-situ
Open wound and/or scabbing
Infection present, or suspected
Non tolerance to wear

7.0 Patient Adjustable Feet and Ankle units

7.1 Indications for prescription of Patient Adjustable Feet and Ankle units

7.1.1 Not provided for a Primary prosthesis as clinically inappropriate.

7.1.2 Provides patient flexibility to change different foot wear throughout the day
Large range of adjustment required for different footwear
Clinical appropriateness

7.2 Contra-indications for use of Adjustable feet/ankles:

Additional weight: consider increased weight of prosthesis
Poor cognitive ability: incorrect use and set up may cause falls
Low mobility
Poor dexterity: patient unable to operate the controls due to poor/weak hands

8.0 Telescoping and Torsion adaptors for Prostheses

- 8.1 Indications for prescription of Telescoping and Torsion adaptor or feet
Short residual limbs
Reduce impact forces
Reduce shear forces
- 8.2 Telescoping and Torsion adaptors will be provided where clinically appropriate and will not be considered for specific sport purposes

9.0 Cosmetic Covers

9.1 Indications for prescription of Cosmetic covers

- 9.1.1 Most prostheses will have a cosmetic outer cover depending upon the individual requirements and patient choice.
These are usually hand shaped dense/flexible foam with a fabric cover (stocking).
There are however other options some of which are provided with in the normal prescription guide and others which can be prohibitively expensive and not provided by the NHS service.

9.2 Premade silicon or plastic cover (component)

Silicone (eg Skinnergy), PVC and other realistic finishes can be provided as clinically appropriate, where the cosmetic outer look of the prosthesis is an important consideration for the individual

9.3 Custom made covers

Custom made covers are not provided by NHS due to high cost and inability to maintain the prosthesis.

9.4 Transfemoral cosmetic covers

A soft foam cover can be provided and matched to shape to the contralateral limb (if possible). Normally fitted with a fabric cover.
The NHS will not provide silicone covers on a transfemoral prosthesis
PVC covers can be provided if appropriate

9.5 Patterned and coloured laminate finishes

Some users prefer not to use an outer cover to the prosthesis. Some special finishes can be added to the socket if appropriate
Laminates are finished with flesh colour pigment. Some users prefer a different finish
A low cost Lycra material or colour pigment can be added into outer layer of lamination to provide a more individual appeal.
It may not be appropriate to use either pigments or Lycra's depending on individual circumstances and technical specifications.

Pattern Lycra's and pigments can only be used if available and appropriate from P&O suppliers.

It may be possible to use fabric provided by the user (if appropriate). However no guarantees regarding finish or effectiveness can be given or implied.

10.0 High cost components

10.1 High cost items: for Derby Prosthetics are identified as individual components with a cost value greater than £3500.

Most prescription items will be covered within this range.

Prosthetists have an ordering limit of £2500 per order. Items up to £3500 are referred onto a manager to authorise

10.2 Items over £3500 normally need to be agreed with a manager or via Special Case Funding

10.3 Exceptions

10.3.1 Microprocessor Knees (MPK). Funding for MPK is currently agreed following an assessment and trial period to establish if functionally appropriate

Funding for MPKs (approx. £12k) is agreed via a separate budget from NHS England

10.3.2 Enhanced prescription via Veterans' Prosthetic Panel (VPP): funding agreed via separate external budget

10.3.3 Prosthetic components already in use by users (Legacy): e.g. KX06.

10.4 Items not normally prescribed within the NHS due to cost

Genium knee

Power knee

Proprio Foot

Running/Sprinting Blades

Sport limb

(List not exhaustive and regular updates required)

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Appendix 1

Derby Prosthetics: Standard Delivery times: Pros codes/Days

<u>Limb Code</u>	<u>Primary</u>	<u>Average standard</u>	<u>Maximum priority</u>	<u>Comments</u>
	Working days	Working days	Working days	
<u>New limbs</u>				
M1	15	30	15	
M2	10	25	10	
M3	10	25	10	
M4	10	20	10	
M5	10	25	10	
M6	15	35	15	
<u>Socket tech</u>				
M16	10	10	10	

<u>Diagnostic socket</u>				
DS	5	10	5	
<u>New sockets</u>				
M17.1	15	30	15	
M17.2	10	25	10	
M17.3	10	25	10	
M17.4	10	20	10	
M17.5	10	25	10	
M17.6	15	35	15	
<u>Major repairs</u>				
M18.1	15	30	15	
M18.2	10	20	10	
M18.3	10	20	10	
M18.4	10	20	10	
M18.5	10	25	10	
M18.6	15	35	15	

<u>Waiting repairs</u>				
M19AR	1	1	1	
M19A	1	1	1	
M19R	1	1	1	
<u>Supply on day</u>				
M20	1	1	1	
<u>Supply postal</u>				
M21	5	10	5	If in stock

Appendix 2

Derby Prosthetics: Activity codes: Comparison table: see below

<u>(A)ctivity Codes</u> Lower Limb Prosthesis		<u>SIGAM GRADES</u>		<u>Blatchford Activity Guide (K0-K4)</u>		
1	A0L	User does not wear a prosthetic limb	A:	Limb wearing abandoned or use of cosmetic limb only.	K0	The amputee does not have the ability to move independently and uses a prosthesis for cosmetic purposes only
2	A1L	User has the ability to use the prosthesis for transfers and walking on level surfaces for short periods of time. Typical of prosthetic demands of a limited household/cosmetic user	B:	Wears prosthesis only for transfers, to assist nursing, walking with the physical aid of another or during therapy.	K1	Indoor Walker – Limited to indoor walking the amputee is able to walk on level surfaces at slow cadence
3	A2L	User has the ability to use the prosthesis on uneven surfaces or to overcome low-level environmental barriers at fixed cadence. Typical of the prosthetic demands of a limited community or household user.	C:	Walks on level ground only, <50 metres, with or without use of walking aids: a = frame, b = crutches/sticks, c = 1 crutch/stick, d = no aid.		
4	A3L	User has the ability to walk/move with variable cadence. This is typical of a user who has the ability to overcome many environmental barriers and may engage in vocational or leisure activities that demand prosthetic utilisation beyond simple locomotion. Typical of the prosthetic demands of an active adult	D:	Walks outdoors on level ground only and in good weather, more than 50 metres, with or without use of walking aids: a = frame, b = crutches/sticks, c = 1 crutch/stick.	K2	Limited Walker – Within a limited outdoor range, the amputee has the ability to walk at slow or medium speed and can manage small obstacles such as curbs, steps and uneven surfaces
5			E:	Walks more than 50 metres. Independent of walking aids except occasionally for confidence or to improve confidence in adverse terrain or weather.		
6	A4L	User has the ability or potential for prosthetic walking needs that exceed basic walking skills, exhibiting high impact stress or energy levels. Typical of the demands of a very active adult or athlete.	F:	Normal or near normal gait.	K3	Active Walker – Daily activities include walking with rapid and variable cadence over uneven terrain and negotiating most environmental obstacles encountered
7	ECA	Extra Contractual Activity: Specialist sports limbs, high definition silicone cosmesis and silicone restoration including digits and C-legs. From national framework agreement prices with a stipulation that this does not exceed 5% of the total caseload.			K4	Very active, Sports participant – Dailey activities that exceed basic walking including rigorous, high impact, high-energy activities like athletics, children's games and rugged work
<u>DAILY USE:</u>		1 = 0-4 hours 2 = 4-8 hours 3 = more than 8 hours				

Appendix 3

Measurement and Ordering Guide for Juzo Compression Stump Shrinkers

All items issued need to be specifically allocated to an individual patient.

When ordering or requesting a Juzo Compression stump shrinker, please supply the following information:

- 1 Patient name and reference number
- 2 Level, side and size required
- 3 Full set of measurements as detailed below:

Below Knee Juzo shrinkers (Transtibial amputee)

Measure circumference:							Meas	Length: 10cm above knee to end
	I / XS	II / S	III / M	IV / L	V / XL	VI / XXL		
10cm above knee	41cm	44cm	47cm	50cm	53cm	56cm	F	Short 30cm
Knee centre	31cm	34cm	37cm	40cm	43cm	46cm	E	Medium 38cm
Stump end	29cm	32cm	35cm	38cm	41cm	44cm	C	Long 46cm

Above Knee Juzo shrinkers (Transfemoral amputee)

Measure circumference:							Meas	Length: Perineum to end
	I / XS	II / S	III / M	IV / L	V / XL	VI / XXL		
Perineum (groin)	44cm	48cm	52cm	56cm	60cm	64cm	G	Short 20cm
Stump end	31cm	34cm	37cm	40cm	43cm	46cm	F	Medium 25cm
								Long 30cm
								X Long 35cm

Guide for Issuing Juzo Compression Stump Shrinkers

Juzo compression socks are normally issued to amputees likely to progress to prosthetic use, approximately 10 days, following surgery.

Main function is to help control oedema, especially when starting to mobilise with the residuum pendant.

The Juzo can be worn all day, but recommend it is removed at night.

An entry into the Patient's Clinical File must be made as part of their treatment plan

CONTRA-INDICATIONS:

Stitches, staples and/or drain tubes still in-situ.

Open wounds and scabbing

Infection present, or suspected

Non tolerance to wear

All above must have Medical approval prior to issuing a compression shrinker.

There are many sizes to accommodate different sizes of residuum.

It is important to ensure that an accurate set of measurements are made to ensure the proper size selection.

Failure to do this could lead to skin or wound breakdown.

In the case of bulbous shapes outside of normal measures, a Juzo can still be used but only under supervision.

If the measures are outside of the range then an alternative control method may need to be found.

Advice can be sought from Senior Prosthetist, Physiotherapy and/or Consultant at ARC

Once issued, the patient needs to have proper instruction in the use of shrinker, to ensure it is donned correctly.

There should be no distal gapping or creases.

Manual dexterity should be tested to ensure independent use (or arrangement made for assistance).

Instruction to be aware of the potential problems and symptoms. Inspection of the residuum before and after use.

If the following sensations or symptoms are evident, the Juzo MUST be removed:

Deterioration of wound condition

Acute infection diagnosed

Pain and/or Burning sensations

Pins and needles sensation

Paraesthesia (altered sensation)

Anaesthesia (loss of sensation)

Redness of the residuum or above the Juzo