How to justify Medical Necessity of advanced prosthetic and orthotic devices

Andreas Kannenberg, MD, PhD
Disclaimer

The recommendations given in this presentation do not guarantee approvals of claims by health insurance companies, but they may help meet the expectations of medical reviewers, increase the chance of successful applications and eliminate many formal reasons for denials.
Agenda

1. What defines “medical necessity“ of a device/drug/treatment?
2. Why do we need the concept of “medical necessity“?
3. The “8 Commandments“ of making your docs fit to demonstrate medical necessity of the requested device.

4. Examples for describing medical necessity of a device for specific patient needs the way medical staff/reviewers expect it
5. Common mistakes to avoid
1. What does define medical necessity?
Medical necessity of a device

= 

Unmet patient need(s)

+ 

Why / how does the requested device meet the currently unmet need(s) and why are less sophisticated/expensive devices unable to do so?

+ 

Proof / evidence that the requested device meets the unmet need(s) better than less sophisticated/expensive devices.
2. Why do we need the concept of “medical necessity“?
Why do we need the concept of “medical necessity“?

…because health insurance companies don‘t want to pay more than is medically necessary for the patient.

… or, in other words, they don‘t want to pay more than they have to.

If two devices deliver the same benefit, why should an insurance pay for the one that is more expensive than the other one?

That is the reason why “medical necessity” needs to be demonstrated, and this need increases with the price tag / price difference of devices.

Inasmuch, the concept of medical necessity is understandable. However, rules and execution may sometimes be quite questionable.
3. The 8 Commandments for making your documentation fit to demonstrate “medical necessity“ of the requested device.
The 8 Commandments

1. Think twice about what you write in your records.

2. Review the coverage criteria of the patient’s insurance and make sure you can check all boxes needed.

3. Make sure your notes match those of the referring/ordering physician.

4. Make it easy to find those entries/facts that you want a reviewer to find.

5. Keep medical justifications brief.

6. Don’t bother medical reviewers with lengthy technical descriptions.

7. Focus on unmet patient needs and how the requested device meets them – functionally, not technically.

8. Back the claims on a device with evidence whenever possible, and tie it to the patient’s unmet needs.
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Think twice what your write in your records

Think carefully about what you write in your records. Anything you write down can and will be used against your claim by medical reviewers.

Every minute you spend thinking about and writing down your notes will save you half an hour or more when writing the medical justification and appeals.
Think twice what your write in your records

Check the coverage criteria of the patient’s insurance and make sure you document that your patient meets all of these criteria. (Commandment #2)

Use as many objective and validated measures as possible to support your clinical judgment (e.g. AMP and/or timed walk tests to substantiate K-level determinations, TUG/FSST to assess risk of falling, etc.).

Enter the results of your validated testing and any other information that may support your claim directly into your medical records. e.g. - activities the patient did prior to the amputation,

- mobility restrictions: activities the patient wants to do but is not able to, activities the patient is struggling with,

- Falls! How often? In which situations/activities?

- patient feedback on the device if the patient is already using it, etc.

No endorsement of any test! They all have strengths and limitations.
## Documenting unmet safety and mobility needs

<table>
<thead>
<tr>
<th>Daily activities</th>
<th>Can the patient do this activity with his/her current prosthesis? Describe difficulties, such as stumbles, falls, compensatory movements, not making it across the street before light changes, inability to change walking speed when needed, etc.</th>
<th>How will the patient be able to do this activity safer/better with the new prosthesis? What function(s) does the new prosthesis offer that will support the patient in doing this activity? Is there published evidence to support this?</th>
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<td>Potential future activities (explain if these differ from prior activities)</td>
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<td>…</td>
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</table>
How to handle issues with the device?

If the patient is already using the device (e.g. C-Brace), describe potential issues as precisely and accurately as possible.

Re-adjustments may be due to a change in the patient’s physical condition and not to the device itself.

Imprecise documentation of “issues“ will always be ruled as “poor quality“ or “immaturity“ of the device, resulting in a denial as “experimental“ or “investigational“.

Don´t try to cover up “issues“, but don´t hit reviewers over the head with them either. They don´t have to be listed in a summary of entries that you may want to bring to the attention of a reviewer. (Commandment #4)
The 8 Commandments

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5. Keep medical justifications brief.

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Example: Anthem MPK policy

**Medically Necessary:**
The use of a microprocessor controlled lower limb prosthesis (for example, Otto-Bock C-Leg device®, Otto-Bock Genium™ Bionic Prosthetic System, the Ossur RheoKnee® or the Endolite Intelligent Prosthesis®) is considered **medically necessary** for transfemoral (above knee) and knee disarticulation amputees when *all* of the criteria set forth in (A) and (B) below have been met:

A. Selection criteria:
1. Individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology and to allow for faster than normal walking speed; **and**
2. Individual has demonstrated the ability to ambulate faster than their baseline rate using a standard prosthetic application with a swing and stance control knee; **and**
3. Individual has a documented need for daily long distance ambulation (for example, greater than 400 yards) at variable rates. (In other words, use within the home or for basic community ambulation is not sufficient to justify the computerized limb over standard limb applications); **and**
4. Individual has a demonstrated need for regular ambulation on uneven terrain or regular use on stairs. Use of limb for limited stair climbing in the home or place of employment is not sufficient to justify the computerized limb over standard limb applications.

B. Documentation and performance criteria:
1. Complete multidisciplinary assessment of individual including an evaluation by a trained prosthetic clinician. The assessment must objectively document that all of the above selection criteria have been evaluated and met.

**Not Medically Necessary:**
The use of microprocessor controlled leg prosthesis is considered **not medically necessary** in all other cases, including when the criteria above have not been met.
Listing and checking all coverage criteria makes the life of a medical reviewer easier – it also makes it easier for them to justify an approval internally.

Medical reviewers have to follow formal administrative procedures and justify their decisions (approvals) to their superiors.

If the patient doesn’t meet some or all of the coverage criteria in the policy, medical reviewers have a hard time justifying an approval internally.

That’s why, do yourself a favor and make sure the patient meets all formal coverage criteria.
Review the coverage criteria of the patient’s insurance and make sure you can check all boxes needed

Use as many objective and validated measures as possible to support your clinical judgment, e.g.

- ABC scale
- Amputee Mobility Predictor (AMP / AMPnoPro)
- timed walk tests (e.g. 10 m WT, 2MWT, 6MWT)
- Timed up and go test
- Four square step test (FSST)

Activity “cheat sheet“ to remind you to ask for activities to meet recurring criteria that often result in denials (e.g. necessity to ambulate on uneven terrain on a regular basis: playing with kids in the yard, play areas, gardening, walking in parks, in the woods, fishing, hunting, use of public transportation, etc.)

No endorsement of any test! They all have strengths and limitations.
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Make sure your notes match those of the referring/ordering physician

The physician’s notes are key!

Let the physician know the coverage criteria of the patient’s insurance and what needs to be documented in the physician’s record.

Obtain a correct prescription/order.

Obtain copies of the physician’s notes on those criteria in the coverage policy that require an examination or appraisal by a physician (e.g. cardiovascular reserve, cognitive abilities, etc.)

Compare the physician’s notes with yours and try to resolve any inconsistencies and discrepancies. Explain discrepancies that you are not able to resolve, e.g. differences in the results of manual muscle tests in the morning and afternoon may be due to fatigue of the patient.
Make sure your notes match those of the referring/ordering physician

Obtain a correct prescription/order

The orthotist noted in his records several times:
“Neurologist Dr. X prescribed 2 C-Braces.“ (value: $150,000)

What did the actual prescription of Dr. X say?

“2 KAFO´s with SPL“ (value: $15,000)

Difference in value: $135,000 !
Make sure your notes match those of the referring/ordering physician

No match of the physician’s and the CPO’s records

The orthotist noted in his records:

“The patient works full-time as a physical therapist.”

What did the physician’s record say on the daily activity of the patient?

- gets up at 8:30
- takes a shower, has breakfast
- makes physician and lawyer appointments
- prepares lunch
- takes a nap
- plays with his kids when they come from school
- socializes with friends in the evening
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Make it easy to find those entries/facts that you want a reviewer to find

Every reviewer is fed up right away if he/she sees 40 pages of paper with no guidance, forcing him/her to read through every single entry.

Result:

- entries that speak for the claim will be ignored or neglected
- entries that speak against the claim will be highlighted and exploited

Keep in mind:

Medical reviewers/auditors

- have to justify approvals of expensive claims.
- are NOT paid for approving unjustified claims!
Make it easy to find those entries/facts that you want a reviewer to find

**Mine your records to support your claim**

Don´t leave medical reviewers with 40 pages of copies of your records without guidance.

Mine your records for all entries that support your claim.

List them in a summary as cover sheet and refer to the date of entry, the page of the copy, and a very brief summary of what the entry says.

Mark these entries in the copy with post-its (**NOT highlighter!** – that would be considered a change of the docs after the fact) to make it easy for the reviewer to find them.
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5. **Keep medical justifications brief.**

6. Don‘t bother medical reviewers with lengthy technical descriptions.

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Keep medical justifications brief

Keep in mind that medical reviewers have only 18-20 minutes per claim!

That‘s why, try to boil the letter down to a maximum of 4-5 pages!

It‘s a hard thing to do! (I know.)

Don‘t bother the reviewer with lengthy technical descriptions! (Commandment #6)

Keep the letter of medical necessity brief, focus on the most important facts, and avoid redundancies.
Keep medical justifications brief

A common mistake to avoid...

Letter of 12-15 pages with multiple repetitions of technical features and details, but no description of clinical benefits.

Example:
Letter of medical necessity for the C-Brace in which the technical features and functions (1.5 pages) were repeated 4 times (=6 pages!).
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8. Back the claims on a device with evidence whenever possible, and tie it to the patient’s unmet needs.
Don‘t bother medical reviewers with lengthy technical descriptions and details

Physicians and nurses are trained to focus on patient needs and (studied / published) patient benefits and risk / adverse event profiles.

The technology behind the patient benefits is - at best - of secondary interest and does usually NOT drive decision making.

“New“ or “state-of-the-art“ technology or technical details such as “gyroscope“ or “the fastest microprocessor“ DO NOT trigger approvals!

*When you are interested in towing capacity and payload of a truck, you won’t appreciate a car dealer explaining to you how a combustion engine works.*

So, don't waste their time with details they are not interested in and focus on those facts that really matter to them (proven patient benefits and risk profiles).
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Medical necessity of a device

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Unmet patient need(s)

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Why / how does the requested device meet the currently unmet need(s) and why are less sophisticated/expensive devices unable to do so?

+ 

Proof / evidence that the requested device meets the unmet need(s) better than less sophisticated/expensive devices.
Build a clear chain of arguments

1. List the unmet safety and/or mobility needs of the patient.

2. Define a goal for fitting the requested device.

3. Match the needs of the patient with the functions of the requested device.
   If possible, refer to publications of studies that have demonstrated superior safety and/or function of the requested device, thus supporting the goal of fitting. Even better if you are able to cite specific results that support your claim.

4. State why less advanced/expensive technology is not sufficient to meet the patient’s safety and/or mobility needs.
   With evidence demonstrating superiority of the requested device, this part can be kept very brief or even skipped.
Documenting unmet safety and mobility needs

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Falls, past injuries, stumbles, fear of falling, lack in balance confidence, activity avoidance...
State a clear goal of device fitting
Address unmet safety and/or mobility needs

What is the primary goal of fitting a new device to the patient?

This may be, for instance,

- reduce falls / risk of falling / risk of injury
- improve mobility/performance in activities the patient has to perform
- reduce the re-occurrence of residual limb wounds/irritations
- reduce asymmetry and compensatory movements to alleviate pain and/or prevent long-term comorbidities
Match unmet needs and fitting goals with device functions

Do not expect any kind of deeper P&O background knowledge of reviewers.

Do not expect them to connect the important dots and facts for you.

**Good news**
In most of the docs, the information to build a strong case is there.

**Bad news**
Often times, this information is reported incompletely, not leveraged properly, and important facts are not connected to build a strong case.
Describe the medical necessity of the requested device in a logical way that an ALJ or independent observer would wonder:

“Why did the insurance deny this device?”
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7. Focus on unmet patient needs and how the requested device meets them – functionally, not technically.
8. Back the claims on a device with evidence whenever possible, and tie it to the patient‘s unmet needs.
Which clinical benefits can be supported by evidence?
Genium/X3 vs. L5856 MPK’s (e.g. C-Leg)

- improved and more consistent, speed-independent toe clearance due to improved swing knee flexion control (Bellmann et al. 2012, Lura et al. 2015)

- improved swing release and toe clearance in small steps (Bellmann et al. 2012)

- safe walking backwards (Kannenberg et al. 2013)

- improved knee flexion and thus toe clearance in slope ascent and descent (Bellmann et al. 212, Lura et al. 2015), greater perceived ease of slope negotiation (Kannenberg et al. 2013)

- tendency to greater ease of uneven terrain negotiation (Highsmith et al. 2014, Kannenberg et al. 2013)


- Greater perceived safety and ease of ADL execution (Kannenberg et al. 2013) and improved prosthetic function (Highsmith et al. 2014)

- improved ability to stand still for longer periods of time (Bellmann et al. 2012)
Which clinical benefits can be supported by evidence?

C-Leg/Compact vs. NMPK’s (1)


- **reduced cognitive demand to walk and improved multi-tasking** (Morgan et al. 2015, Kannenberg et al. 2014, Hafner et al. 2009, Williams et al. 2006)

- **potential to increase overall mobility / K-level** (Kannenberg et al. 2014, Hafner et al. 2009, Kahle et al. 2008)
Which clinical benefits can be supported by evidence?
C-Leg/Compact vs. NMPK´s (2)

- Benefits to K2 patients:
  - Up to 80% reduction in falls, reduced risk of falling, improved balance confidence
  - 14-25% faster walking speed on level ground
  - 20% faster walking speed on uneven terrain
  - 30% faster slope descent, improved quality of stair descent
  - Improved performance in activities of community ambulation – about 50% of K2
  - Improved mobility level to K3
  - Improved indoor ADL performance

Which clinical benefits can be supported by evidence?

MP controlled ankles/feet

- increased toe clearance and reduced likelihood of catching an unseen obstacle (Johnson et al. 2014, Rosenblatt et al. 2014)

- reduction of soft tissue loading and pressure during walking, especially on slopes, uneven terrain, and stairs (Portnoy et al. 2012, Wolf et al. 2009)

- reduction of braking forces and the perception of having “to climb over the foot“, resulting in increased self-selected walking speed (DeAsha et al. 2013a, 2013b and 2014)

- more symmetrical movement patterns, reduced compensatory movements and residual limb loading during slope ambulation (Fradet et al. 2010, Darter et al. 2013)

- more symmetrical movement patterns, reduced compensatory movements and residual limb loading during stair ambulation (Alimusaj et al. 2009)
Which clinical benefits can be supported by evidence?

**Harmony VASS**

- **reduced risk of falling, improved balance** (Samitier et al. 2014, Kahle et al. 2014, Ferraro et al. 2011)

- **improved walking performance and capabilities** (Samitier et al. 2014, Kahle et al. 2014 and 2013)


- **reduced pistoning and interface pressure** (Kahle et al. 2014 and 2013, Street et al. 2006, Beil et al. 2002, Board et al. 2001)

- **superior patient preference and/or quality of life** (Samitier et al. 2014, Kahle et al. 2013)
Which clinical benefits can be supported by evidence?

C-Brace

- patients are able to use knee stance flexion during level walking (Schmalz et al. 2014)
- walking speed-adaptive swing control (Schmalz et al. 2014)
- reciprocal slope and stair descent (Schmalz et al. 2014)
- reduction of use of assistive devices (Schmalz et al. 2014)
- improved perceived orthotic function, safety and ease of ADL execution (Pröbsting et al. 2016)
How can you leverage the existing evidence?

Create brief summaries of study results with references as textblocks. Study results don’t change and are “reusable“.

OR

Use the “ready-to-use“ evidence summaries of Ottobock.

They will be sent out with a copy of this presentation next week and are available on our Product Webinar website: https://professionals.ottobockus.com/Product-Webinars

Evidence for the C-Leg
Why is less advanced technology not sufficient?

YOU are the expert – leverage your knowledge!

Explain why less sophisticated/expensive technology is not appropriate to meet the needs of the patient and the fitting goal(s).

Citing clinical studies that have demonstrated superiority of the requested device reduces the need to explain the limitations / restrictions of less advanced technology.

If there are no studies, describe the limitations / restrictions of less advanced technology and how it would limit / restrict the patient in achieving his/her needs and goals.

Tip: Create and use text blocks for describing the limitations of devices that you have to disqualify on a regular basis.
Stability and function in non-MP controlled knees

<table>
<thead>
<tr>
<th>Knee flexion during weight bearing</th>
<th>Stability*</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>No K1 / K2</td>
<td>No K2 / K3</td>
<td>Unlimited (yielding) K3 / K4</td>
</tr>
<tr>
<td>Knee mechanism(s)</td>
<td>locked knee, friction brake knee, 4-bar polycentric knee</td>
<td>Multiaxial knees with &gt;4 axes, knees with bouncing adapter</td>
</tr>
<tr>
<td>Terrains supported (+) or not supported (-) for negotiation</td>
<td>+ walking on level ground no support of stance flexion for shock absorption</td>
<td>+ walking on level ground, stance flexion for shock absorption</td>
</tr>
<tr>
<td></td>
<td>- walking on uneven ground</td>
<td>+ walking on slightly uneven terrain alternate descent of shallow slopes (≤5°)</td>
</tr>
<tr>
<td></td>
<td>- alternate slope and stair descent</td>
<td>- no support of negotiation of heavily uneven terrain</td>
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</tbody>
</table>

*stability = prevention of knee collapse during level walking

Stability ≠ Safety

Safety = stability during level walking, + stability during walking on uneven terrains, slopes, stairs + toe clearance + stumble recovery
Hydraulic MPK’s combine safety and function and overcome their inverse relationship in NMPK’s

**Safety**
- ✓ reduced stumbles and falls
- ✓ reduced indicators for risk of falling
- ✓ improved balance
- ✓ improved confidence

**Function and mobility**
- ✓ Improved negotiation of stairs, slopes, obstacles, and uneven terrain
- ✓ reduced cognitive demand and improved multi-tasking
- ✓ potential to improve overall mobility level
- ✓ superior patient preference and quality of life

Hydraulic MPKs have demonstrated their benefits in K2, K3, and K4 amputees.
## Restrictions of locked KAFOs and SCOs

<table>
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<tr>
<th>Locked KAFO</th>
<th>Stance Control Orthoses (SCO)</th>
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<tbody>
<tr>
<td>- restores walking capability</td>
<td>- reduces/eliminates compensatory movements in level walking</td>
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<tr>
<td>- forces patient to walk with stiff orthotic leg</td>
<td>- difficult to safely operate on terrains other than level surface</td>
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<tr>
<td>- requires substantial compensatory movements</td>
<td>- Many patients lock their SCO on uneven terrain, slopes, and stairs.</td>
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<tr>
<td>- hip hiking</td>
<td>- Thus, SCOs require the same compensatory movements as locked KAFOs on non-level surfaces.</td>
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<tr>
<td>- circumduction</td>
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<td>- vaulting on the intact side</td>
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<tr>
<td>- may result in premature degeneration of the lumbar spine</td>
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<tr>
<td>- very difficult to safely negotiate terrains other than level surface</td>
<td>- appropriate for patients who mainly walk on level ground/indoors, but not for patients who have to negotiate uneven terrain, slopes, and stairs on a regular basis</td>
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4. Examples for describing medical necessity of a device for specific patient needs in the way medical staff/reviewers expect it.
The following examples for describing the medical necessity of different devices for patients with specific needs are intended to give you some helpful guidance.

The actual letter or statement of medical necessity must, of course, be somewhat more elaborate and detailed, although not lengthy.

Keep the letter of medical necessity short, focus on the most important facts, and avoid redundancies.
Example 1
AK amputee who falls often – MPK (C-Leg)

Unmet needs
Mr. X falls twice a week when using his current NMPK (e.g. hydraulic knee) and has sustained several injuries (e.g. radial fracture, wrist sprain, concussion, bruises) that required hospitalization/medical attention in the past.

Fitting goal: To reduce the risk of falling and injuries.

Match needs with device functions
Consistent scientific evidence that the C-Leg significantly reduces falls by up to 80% as well as indicators of the risk of falling.

Why is less advanced technology not appropriate?
Mr. X is using an NMPK and falls twice a week. Downgrading him to a more stable NMPK would restrict his overall mobility (reciprocal relationship between safety and function in NMPK’s). Only an MPK provides the combination of required safety and support of mobility and activities (see references).
Example 2

Active dysvascular BK amputee – Harmony vacuum socket

Unmet needs
Mr. X is very active (K3) and travels throughout New England every day as a sales representative. His mobility is restricted by decreasing socket suspension over the day due to shrinking residual limb volume as well as recurring skin wounds and blisters due to relative movements between his socket and residual limb.

Fitting goal
To keep socket suspension constant by stabilizing residual limb volume and to prevent or heal skin wounds by eliminating relative movements between socket and residual limb.

Match needs with device functions
A recently published clinical study (Samitier et al. 2014) has demonstrated that dysvascular BK amputees with K3 mobility presented statistically significant improvements in validated indicators of the risk of falling and validated outcome measures of balance and overall walking capabilities. Furthermore, a clinical trial (Traballesi et al. 2012) and two case studies (Hoskins et al. 2013, Traballesi et al. 2009) have shown that a vacuum-assisted socket allows for using the prosthesis in spite of residual limb wounds without interfering with wound healing or causing pain or discomfort. Residual limb wounds healed equally fast while continuously using the prosthesis with the Harmony socket as in the control group that had completely discontinued prosthesis use, which is not an option for Mr. X.

Why is less advanced technology not appropriate?
The benefits of the Harmony vacuum socket were found by comparing it to various standard sockets, including suction sockets. The described benefits are specific to vacuum socket systems.
Example 3
Patient with progressive neurologic condition – C-Brace

Unmet needs
Mr. X. has a history of inclusion body myositis (IBM) for 8 years resulting in a severe paresis of all muscles of both legs. He is no longer able to walk independently without an orthosis (refer to results of MMT).

Fitting goal
To keep Mr. X ambulatory and independent and prevent him from becoming wheelchair-bound for as long as possible.

Match needs with device functions
The MP controlled hydraulic C-Brace is the only orthosis that allows for safe and nearly physiologic ambulation on all terrains (Schmalz et al. 2014). There is a good chance that Mr. X will not require any additional walking aids to ambulate with the C-Braces. The slow progression of the IBM in the past years (refer to the physician’s records) indicate that Mr. X may be able to use the C-Braces for an acceptable period of time.

Why is less advanced technology not appropriate?
Locked KAFO’s on both limbs are difficult to safely operate, require massive compensatory movements and the use of two crutches. The crutches cause considerable stress to the upper limb joints and block the hands for carrying objects or other activities. Stance control orthoses work reliably on level surfaces only, but are difficult to safely operate on non-level surfaces (Zacharias et al. 2012). Most patients lock them on non-level surfaces, resulting in the same mobility restrictions as for locked KAFO’s.
Specific consideration for orthotics
Progressive neurological conditions

If you apply for a sophisticated orthosis (e.g. C-Brace) for a patient with a progressive neurological condition, you may want to collect as much information as possible on the speed of progression of the disease in the past.

The speed of progression in the past (3-5 years) is critical as the insurance wants to know for how long the patient will be able to use the device. Slow progression is an indicator, although not a guarantee, that the patient may be able to use the device for a longer period of time.

Rapid progression in the past speaks for a poor prognosis of the condition with little willingness of the insurance to approve the device.
Example 4
Patient stable neurologic condition – C-Brace

Unmet needs
Mr. X sustained an incomplete spinal cord injury with pareses of the muscles of both legs 28 years ago and has since been walking with an AFO on the right leg and a locked KAFO on the left leg (refer to results of MMT). The necessary compensatory movements to operate a locked KAFO (hip hiking, pelvic obliquity, circumduction) resulted in accelerated and extensive degeneration of the lumbar spine that required lumbar decompression and fusion surgery last year. As a result, Mr. X is no longer able to perform the compensatory movements necessary to safely operate a locked KAFO.

Fitting goal
To allow for physiologic ambulation with no need for compensatory movements.

Match needs with device function
The MP controlled hydraulic C-Brace is the only orthosis that allows for safe and nearly physiologic ambulation on all terrains with no or only minimal compensatory movements (Schmalz et al. 2014). There is a good chance that Mr. X will not require any additional walking aids to ambulate with the C-Braces.

Why is less advanced technology not appropriate?
Locked KAFO: Due to spinal fusion surgery last year, Mr. X is no longer able to perform the necessary compensatory movements without considerable pain. Stance control orthoses are not suitable as they work reliably on level surfaces only, but are difficult to operate on non-level terrains (Zacharias et al. 2012). Most patients lock them on non-level surfaces. As Mr. X has to ambulate on slopes and uneven terrain on a regular basis (give examples), SCO technology is not a suitable orthotic technology for Mr. X.
Example 5
AK amputee who lives on a farm/ranch (uneven terrain) – Genium/X3

**Unmet needs**
Mr. X lives and works on a farm/ranch where he always has to walk on hilly and uneven terrain to perform his daily routine and work.

**Fitting goal:** To improve safety and mobility on hilly and uneven terrain.

**Match needs with device functions**
Scientific research has shown that slopes (uneven terrain is a permanent change between inclines and declines) can be performed in a significantly safer (greater toe clearance) and more physiologic manner (more weightbearing of the prosthetic leg) using the Genium (or X3) than standard MPK’s without pre-flex function (Lura et al. 2014, Highsmith et al. 2014, Schmalz et al. 2014, Bellmann et al. 2012).

**Why is less advanced technology not appropriate?**
Research has shown that standard MPK´s without pre-flex function allow for less toe clearance and prosthetic side weightbearing during slope ambulation than Genium/X3. Genium/X3 may therefore reduce the risk of falling (see references above) and developing longer-term comorbidities of the musculoskeletal system in a similar manner as shown for standard MPK´s as compared to NMPK´s (Kaufman et al. 2012).
Example 6

AK amputee who has to negotiate stairs, slopes, etc. – MPK (C-Leg)

Unmet needs
Mr. X has to negotiate stairs, slopes, and uneven terrain on a daily basis (give examples).

Fitting goal
To improve his ability to negotiate stairs, slopes, and uneven terrain.

Match needs with device functions

Why is less advanced technology not appropriate?
Research has shown that these activities are performed less safe and in a less physiologic manner with NMPK’s (references). Use of the C-Leg may reduce the risk of falling (see references above) and longer-term comorbidities of the musculoskeletal system (Kaufman et al. 2012).
Example 7
BK amputee who trips on a regular basis – MP ankle

Unmet needs
Mr. X trips several times a week using his standard prosthetic foot with a considerable risk of falling and sustaining injuries that may require hospitalization/medical attention.

Fitting goal
To reduce the risk of tripping, falling, and sustaining injuries.

Match needs with device functions
Scientific studies have shown that hydraulic and MP ankles increase maximum toe clearance and reduce the risk of tripping in below-knee amputees compared to standard ESR feet (Johnson et al. 2014, Rosenblatt et al. 2014).

Why are less advanced and other hydraulic and MPA ankles not appropriate?
Research has demonstrated that standard prosthetic feet provide less toe clearance and are thus associated with a higher risk of tripping than hydraulic and MP ankles (see references).
5.
Common mistakes to avoid
Common mistakes
Chain of arguments lacks medical logic

Patient with incomplete SCI had been using a locked KAFO for 30 years, resulting in accelerated and extensive degeneration of the lumbar spine that required spinal surgery 12 months ago.

“Medical necessity“ as described by the orthotist:
The patient is not able to walk with a locked KAFO and needs a C-Brace.

Why does this “medical necessity“ lack medical logic?
Common mistakes
Chain of arguments lacks medical logic

Why does this “medical necessity“ lack medical logic?

…because the patient has walked with a locked KAFO for 30 years.

The logical medical necessity for the C-Brace is:
Due to the spinal degeneration and surgery the patient is **NO LONGER** able to walk with a locked KAFO and do all compensatory movements (hip hiking, pelvic obliquity, circumduction) to safely operate it.
Common mistakes
Incomplete information and missed opportunities

K-level determination was reported to have been corroborated with the 10 m walk test and the timed up and go test – but results were not reported.

C-Leg was reported to “...have buckled frequently, unexpectedly, and more recently caused the patient to fall several times.“
(12 year old, failed C-Leg, request for replacement)

It is unclear if the C-Leg has caused issues right from the beginning or just since it has failed.

Patient suffers from hip pain due to OA in the sound leg, is restricted and needs walking aids when the 12 year old C-Leg is failing. (one of the denial reasons)

Patient was fitted a loaner C-Leg because the failed one was unsafe. No information about how the patient did when she was using the loaner (hip pain? Need for walking aids?)
Common mistakes
Inconclusive or misleading videos

If you intend to support your claim with videos, please remember the following points:

- If the patient is using another (no longer sufficient) device, don’t shoot videos with the requested device vs. no device only, but vs. the current device in situations that clearly illustrate its limitations.

- Don’t shoot videos of situations that do not demonstrate a benefit of the requested device (e.g. climbing stairs with C-Brace in a patient with quad paresis).
Medical necessity of a device

= 

Unmet patient need(s)

+ 

Why / how does the requested device meet the currently unmet need(s) and why are less sophisticated/expensive devices unable to do so?

+ 

Proof / evidence that the requested device meets the unmet need(s) better than less sophisticated/expensive devices.
Medical necessity of a device

Unmet patient need(s)

+ Why / how does the requested device meet the currently unmet need(s) and why are less sophisticated/expensive devices unable to do so?

+ Proof / evidence that the requested device meets the unmet need(s) better than less sophisticated/expensive devices.
Medical necessity of a device

= 

Unmet patient need(s)

+ 

Why / how does the requested device meet the currently unmet need(s) and why are less sophisticated/expensive devices unable to do so?

+ 

Proof / evidence that the requested device meets the unmet need(s) better than less sophisticated/expensive devices.
Last but not least...
Take advantage of Ottobock’s reimbursement service

Let us have a look over your documentation and letter of medical necessity early in the process.

Please mind that you cannot take back what you have already submitted to the insurance (neither can we).

Three days prior to the deadline for the last level of appeal is even too late for us.

Download the “ready-to-use“ evidence summaries for C-Leg, Genium/X3, Harmony VASS, MP controlled ankles/feet, and C-Brace from our Product Webinar website:
https://professionals.ottobockus.com/Product-Webinars
Thank you for your attention

Questions....?

Andreas Kannenberg, MD, PhD
Phone 512-806-2605
Cell 612-532-1916
andreas.kannenberg@ottobock.com