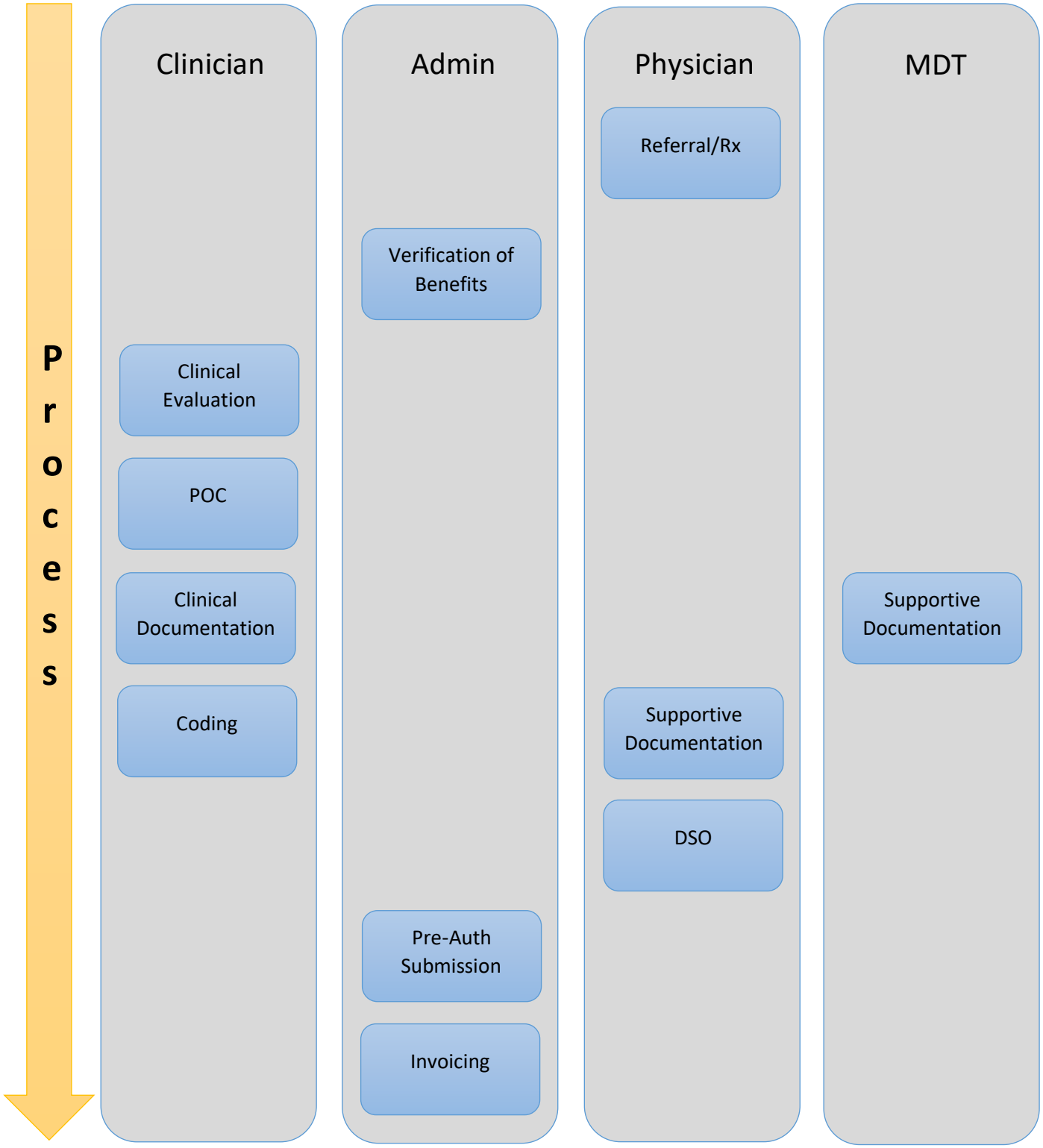
Clinically based documentation guidance for RevoFit® submissions



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Clinical documentation process

Documented in the patient chart.

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Patient history, Existing prosthetic users

Documented in the patient chart.

Document patient reported comments regarding previous and current experiences with their prosthesis including:

- Incidences of socket adjustment
    - Timeline
    - Frequency
    - Describe the issue.
    - What did you do?
    - What was the effect?
- Periods of inability to use the prosthesis.
- Weight gain/loss
- Pain
- Discomfort
- Allergy
- Difficulty with donning/doffing
- Tissue irritation
- Skin breakdown
- Areas of redness that take longer than 20 mins for normal tissue coloring to return.

Patient comments may point toward specific areas the clinician may wish to pay particular attention to in his/her physical examination. Where applicable relate patient reported comment to your findings in examination to describe the patient story.

Document any issues related to:

- Fluctuations in residual limb volume related to:
    - Diet
    - Activity
    - Comorbidity
    - Climate
- Fit issues:
    - Pistoning
    - Rotation
    - Bulbous distal end
    - Loss of suspension
    - Instability
    - Discomfort when seated.

Confirmation of volume fluctuation may be assisted by patient self-measurement. If detail can be obtained it may be entered into the medical record as patient reported detail and could assist in confirming a RevoFit system as a medically necessary option for the patient.

Patient history, New prosthetic users

Documented in the patient chart.

With no patient history to report or document, clinical documentation related to the patient examination and POC is required to describe the rationale for provision of adjustable socket technology. There is perhaps a stronger case for the provision of adjustable technology for new prosthetic users in relation to expected changes in the shape and size of the residual limb can be accommodated by patient adjustable socket technology. Residual limb changes may compromise the socket fit, functionality, and comfort:

- During the day
- Overnight
- Activity related.
- Over a longer period as the residual limb shape matures

The maturation period for the residual limb to achieve a stabilized volume typically varies between 12 & 18 months. Even after this period fluctuations in volume are still likely in relation to weight gain/loss, diet, comorbidity climate etc.

It is not unreasonable to expect that a newly amputated prosthetic user will encounter some or all the issues of an existing prosthetic user. The primary indication for provision of the RevoFit system is to accommodate changes in the residual limb volume and to provide a patient adjustable suspension system.

- Document reasonably expected patient benefits
- Include any of the areas referenced for an existing prosthetic user (previous page)

Physical/visual examination

Documented in the patient chart.

Carried out by the clinician (prosthetist) the physical examination may begin with visual and or a hands-on palpation examination of the residual limb.

If considering adjustable socket technology, you may consider the following:

Did the patient report and/or can you confirm?

- Fluctuation in residual limb volume
- The existence of skin abrasion
- Areas of redness that take longer than 20 minutes to return to a normal color.
- Hypersensitivity
- Possible neuroma
- Presence of bone spur
- Signs of allergic response
- Indications of a lack of total contact

Document the following:

- Patient reported comments/difficulties.
- Observed concerns/issues.
- Proposed treatment clinical solution
- Reasonably expected success resulting from the proposed clinical solution.
    - How and during which required activities of daily living
    - Vocational activity
    - Avocational activity

Examination/evaluation of current components (if relevant)

Documented in the patient chart.

Focusing on the socket.

Replacement of a socket requires the same degree of documentation as any other component. Requirements of medical necessity include:

Confirmation of a requirement to replace the current socket in relation to:

1. A change in the patient presenting condition.
2. Current socket no longer fitting.
3. Current socket broken/damaged beyond economical repair.
4. No further adjustment would render the socket a comfortable or functional.

Ensure documentation of specific detail for any of the above obtained from your evaluation and reference detail you were advised of by the patient in addition to the findings of your physical and visual examination.

Did the patient report and/or can you confirm?

- Change or fluctuation in patient weight.
- Change or fluctuation in residual limb volume.
- The socket rotates on the residual limb.
- Pistoning?
- Poorly fitting socket.
- A lack of total contact.
- Suspension is compromised or ineffective?
- Difficulty donning and doffing the prosthesis?

Having documented a reasonable case to replace the existing socket you must then provide a clinical rationale for the proposed replacement socket with adjustability. Document:

1. The proposed solution functions.
2. Confirm the patient is capable of adjustment.
3. Why the patient is expected to benefit from adjustability.
4. The required activities of daily living where adjustability can reasonably be expected to assist in completion of his/her required activities of daily living.

Plan of Care (POC)

Documented in the patient chart.

Setting out a POC is a recommended addition to your clinical documentation. Establish a plan of care for your patient. The patient may have yet to receive a prosthesis as a new amputee, however, based upon your evaluation you can discuss reasonably expected progress from here. Discuss with your patient and document the results. As your patient progresses in their rehabilitation you can update the plan of care and you can also refer to it when seeking to replace or update componentry. In doing so you can bring subsequent evaluations into context with the plan of care, which is, a planned progression rather than a collection of individual evaluations. Time spent at the beginning is time well spent.

A plan of care is a great opportunity to set the bar of rehabilitation in a reasonable place. You can update the plan at any time based on progress or otherwise. However, when completed with good effect it offers an opportunity to reference progress form an initial patient encounter or evaluation and confirm when goals are met. As such it is a great tool to measure progress and is useful when a patient is ready to move onto a different device to accommodate changes on the presenting condition or improved functionality. A plan of care will be appreciated by pay sources as further evidence of outstanding patient care.

A POC should include:

- Your reasonable expectations of your patient's progress related to:
    - Recommended/Requested/Prescribed or provided prosthetic care.
    - Additional therapy if indicated.
    - Current and possible future functional level.
    - Current and possible future prosthetic provision.
    - Reasonably expected progress.
    - Possible changes in componentry with progress.
    - Updates or changes based on subsequent evaluation.

Example:

Patient may have expressed a desire to return to work or a specific hobby/activity. You may discuss your thoughts on reasonably expected progress toward this. Include:

- Rationale
- Timeline
- Motivation
- Ability
- Support
- Opportunity

Description of proposed provision

Documented in the patient chart.

When considering provision of adjustable socket technology, there is a requirement to differentiate the requested provision from a non-adjustable socket. One method is to simply compare the two options.

When seeking approval and reimbursement for a L5999 you must overcome the 'assumption' that what you are providing is an 'add on' or a means to increase reimbursement.

Options to consider:

- Include images of a conventional and a RevoFit System Socket
- Describe the differences in:
    - Additional clinical time
    - Socket design
    - Fabrication
    - Patient instruction

Compare the above to:

- Patient history of socket adjustment
    - Past frequency
- Cost and inconvenience of multiple clinic visits
- Quality of life issues
- Discomfort
- Reduced activity

Expected patient benefits of proposed provision.

Documented in the patient chart.

In addition to evaluation detail

When considering provision of adjustable socket technology, the requirements of medical necessity must be met to be reimbursed by any payer.

There are several ways to approach documentation, but the overall intent is to confirm justification for the provision of the proposed clinical solution. In the case of the RevoFit we seek to confirm the benefits of patient adjustability. To do so we must address specific questions in our supportive clinical documentation and/or application for reimbursement:

1. Why does the patient need an adjustable socket?
2. How and during which required activities of daily living is the patient expected to benefit from adjustability?
3. What are those activities of daily living?
4. What are the expected consequences of not providing adjustability?
    a. Discomfort
    b. Difficulty donning/doffing
    c. Reduced activity
    d. Reduction in comfort
5. Would it result in a reduction in required activities?
6. If yes, what are the activities?

Additional clinician evaluation (PT/OT etc.)

Included in the patient chart.

Where possible gathering additional supportive clinical documentation is a positive. A multidisciplinary team approach to patient care has a greater likelihood of approval over a single clinician who may be looked upon as a financial beneficiary of the process.

- Include copies of PT/OT documentation
- Reference and include it in your request for approval.
- Include clinical tests if relevant.
    - Amp Pro
    - Amp NoPro
    - TUG
    - 2MWT

Coding

Documented in the patient chart.

We recommend use of the following coding language:

L5999 Addition to lower extremity, residual limb volume management, patient adjustable suspension system.

80-character detail: *Product code or reference #* followed by: residual limb volume management, patient adjustable suspension system.

Physician documentation

Included in the patient chart.

The prescribing physician leads the process of patient care.

Supportive, corroborative physician notes are required by CMS and increasingly by commercial insurers. Obtaining sufficiently supportive notes can be difficult. We recommend not sending a copy of your own clinical notes with a request the physician signs and dates them. It is likely that notes obtained in this fashion would be dismissed as a provider generated document. It is reasonable to support the physician and offer some assistance, but spoon-feeding notes is not a helpful solution.

CMS requires:

It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

Physician notes should corroborate the clinician documentation and be supportive of the process. Typically, physician notes should include:

- Current and expected functional level.
- Rationale for replacement of current componentry (if applicable)
- Supportive narrative and a reasonable expectation the patient of success with the prescribed clinical care within a reasonable time period.

Information that could be included in physician notes:

1. Specifics of physician patient evaluation/interaction
2. Patient motivation to return to previous activities.
3. Patient motivation to complete activities that are currently challenging (and why).
4. Familial support
5. Employment status or intention

Detailed Standard Order (DSO)

The DSO replaced the Detailed Written Order (DWO) and is the only supplier prepared document a provider can prepare for a physician to review, sigh and date. The DSO although required is not considered to be a part of the medical record.

Preparation of prior authorization request document (as needed)

Included in the patient chart.

Typically, an office administrator will have the responsibility of compiling a prior authorization request (where applicable). As the person responsible for obtaining approval/reimbursement the administrator may or may not request additional assistance from the clinician in crafting/reviewing a submission to insurance. The prior authorization should serve the following objectives:

- Describe the requested service.
- Provide clinical justification for a change or replacement & include:
    - Patient history.
    - Patient reported detail.
    - Clinician evaluation.
    - Patient issues or difficulties.
    - Confirm rationale for replacement of components.
    - Describe proposed prosthetic solution.
    - Confirm rationale for provision.
    - Where possible confirm how the provision is within the payer medical policy.
    - Include MDT generated documentation.
    - Include supportive physician documentation.

Administratively based documents

Included in the patient chart.

- Practice administrator
    - Verification of benefits
    - Out of pocket
    - Copayment
- Compilation of DSO
- Requesting DSO from prescribing physician
- Requesting copies of the medical record pertaining to the patient provision
- Patient liaison

Required forms.

In the clinical process:

DSO – Requested from physician after evaluation and coding.

In the billing process:

Typically, billed EDI (Electronic data interchange)

May be a paper submission using HCFA 1500 form.

Prior Authorization vs Pre-Determination

Prior authorization:

A request for approval for services in advance of provision

Pre-Determination:

Confirmation a patient is enrolled in a plan with a payer and the service is a covered benefit.

Prior authorization is the process of reviewing a payer policy requirement, evaluating, documenting and submission of the required documents to a payer for review. If approved the service may proceed with the expectation of reimbursement at the prevailing contracted rate(s)

The main difference between the two is that Pre-Determination merely confirms that a particular item or service is included in the patient plan. It does not confirm that you have met the required policy for provision and reimbursement. Put simply, if the patient is confirmed to be a candidate and the correct administrative process is followed, the service would be reimbursed at the prevailing contracted rate.