



Smart Pyramid™ Reimbursement Information

Orthocare Innovations has compiled information to help obtain reimbursement for the Compass™ instrumented Smart Pyramid™ to be used definitively in lower extremity prosthetics. The documentation for justifying reimbursement must be tailored uniquely for the patient and their prosthetic needs. Please contact Orthocare Innovations at 800-672-1710 if you have any questions.

Documents to submit

- Letter of Medical Necessity by Doctor
- Letter of Medical Necessity by Prosthetist
- Prosthetists initial evaluation notes
- Suggested Smart Pyramid™ script language
- Physician script, specifically describing Smart Pyramid™ as a separate line item
- Compass™ technical product summary
- Compass™ patient information summary
- Compass™ alignment research summary
- Clinical Compass™ documentation including pictures and Compass™ graph printouts

Letter of Medical Necessity Overview

This document is to assist the physician and practitioner to provide justification and documentation for the use of a Compass™ instrumented Smart Pyramid™ system. There are common elements of a good letter, which will need to be included to provide the funding agency with the information needed to justify payment. A well-structured letter will provide a better argument for the necessity of the system and will make it easier to provide further information if the claim is denied. Orthocare Innovations can assist you with further information as needed to create a successful provision of service and payment.

Keep in mind that the reviewers of the letter are typically not experts in prosthetics or gait analysis; so use easy to understand descriptions of the Compass™ and its benefits.

Each letter should be written for the specific patient with a unique description of the patient and why the Smart Pyramid™ is a medically necessary component of the prosthesis.

When you submit your claim to the payer, it is important to include all of the necessary information to process the claim. The following steps will improve the reimbursement process.

Writing an Effective Letter

1. Introduce who you are, positioned as a consultant for the doctor, having evaluated the patient. Explain your qualifications and relation to the patient to establish your credibility. Be sure to provide a copy of this letter to the doctor, so that it can be included in the doctor's patient file as well.
2. Describe the patient, patient's condition (including residual limb condition and other relevant medical conditions), patient's history, type and/or condition of prosthesis, typical use of prosthesis (including patient's typical daily use, patient's goals, and how they plan to reach those goals – i.e. physical therapy), type of prosthesis or intervention recommended, and integration of the Compas™ instrumented Smart Pyramid™. Be sure to refer to the patient by name, describing their family status, job, and other pertinent information making them a person, not just a policy-holder.
3. Discuss specifically why this patient's alignment is critical to their overall prosthetic success – i.e. sensitive residual limb skin, balance impairment issues, overweight, short residual limb, etc. Each of these items, and others, can be directly addressed and benefited by using the Compas™ system.
4. Provide rationale for needed clinical intervention – i.e. new foot, new socket, etc. Discuss why current prosthesis limits the patient's functional abilities. Use descriptions such as “in my examination of the patient...”, “it is my recommendation the patient will need...”, and “patient A needs item B because of reason C.”
5. Prosthetic letter of medical necessity should include 2 to 3 paragraphs specifically outlining the Smart Pyramid™ technology in detail. Use definitive language (i.e. enables, guarantees, etc) when describing the Smart Pyramid™ usage. Describe that the Smart Pyramid™ provides real-time microprocessor based objective alignment data, and quantifies alignment specific adjustments to improve clinical outcomes. Describe how the Smart Pyramid™ accomplishes this – through integrated sensors, electronics, and advanced logic based software. Describe how the Smart Pyramid™ minimizes or eliminates the effects of suboptimal alignment such as discomfort, bruising and skin breakdowns, pain, possible infections, reduced confidence, and reduced levels of activity.
6. Provide a clear introduction of the Compas™ system, specifically explaining how using the Smart Pyramid™ will improve documentation of the functional outcomes and long term success of the patient (see Compas™ Instrumented Smart Pyramid™ Brief Overview and Benefits to the Patient sections below

- for further details). Make sure to use easy to understand, yet definitive language, as the person reviewing the letter likely has limited knowledge of alignment and prosthetic issues. Discuss how the Smart Pyramid™ will be used on an on-going basis with the patient.
7. Explain how you anticipate the use of Compas™ will lead to lower overall costs to the payer and a better patient outcome. (see Compas™ Instrumented Smart Pyramid™ Brief Overview and Benefits to the Patient sections below for further details)
 8. Send the letter, with reference to the particular prescription or case number to the doctor for their files as well as to the payer source.
 9. Include Compas™ Technical and Patient Product Summaries, as well as Compas™ Alignment Research Summary along with the letter so that the reviewer has additional information as necessary: [see Compas™ Brochure](#). Include a copy of the doctor's prescription with the letter and reference the prescription to link the documents.
 10. Include Compas™ reports of pre and post-clinical intervention, and provide clear and easy to understand explanation of the difference. For example, capture Compas™ data prior to replacing a broken prosthetic foot, and after the new prosthetic foot is integrated to the prosthesis, and explain the imposed force differences from the graph. In fact, it is generally helpful to keep the patient's doctor updated on the patient's status through sending a copy of the Compas™ data from each visit. It will further justify the use of the Smart Pyramid™ if the reports are in the doctor's medical records as well.

Each patient is unique and the letter of medical necessity (LMN) should reflect the individual nature of custom prosthetics. There are basic functions that the Compas™ system will afford for the wearer that will provide them with improved outcomes, which will need to be well outlined.

Compas™ Instrumented Smart Pyramid™ Brief Overview

It is important to use your own wording and description of the Smart Pyramid™ technology, in order for your claim or appeal to not be flagged. Multiple claims with manufacturer generated component descriptions are subject to flagging, and possible further denial or delayed payment.

The Compas™ system consists of a scientific grade instrumented modular pyramid, which interfaces with custom software for analysis of the forces acting in the prosthesis and the patient's limb while wearing the prosthesis. Until now it has been difficult to get an accurate measurement of the prosthetic alignment and the forces in a prosthesis acting on the amputee's skin without dedicated and very expensive gait lab equipment. With the Compas™ instrumented Smart Pyramid™, it is possible to quickly and accurately assess the alignment of the prosthesis and document accurate force data for better clinical outcomes for the patient.

Through providing this objective, measurable outcome data, the prosthetist is able to optimize functional capability for lower limb amputees. Use of the Compas™ Instrumented Smart Pyramid™ allows the prosthetist to better align the prosthesis to the patient, ensuring proper force distribution within the socket, resulting in fewer socket related adjustments and replacement sockets, improved residual limb health, and greater safety and security within the prosthesis.

Until now, alignment of the prosthesis was solely subjective in nature, which resulted in less than optimal force distribution within the socket, and the need for numerous follow-up visits for socket related adjustments and issues. Many of these socket-fitting issues can be eliminated through the use of the Compas™ instrumented Smart Pyramid™ by allowing the prosthetist to better align the prosthesis on the patient. It allows the prosthetist to see objective illustrative information about the alignment and socket forces that was previously not able to be seen.

Literature supports that typical static and visual dynamic alignment results in inconsistencies and lack of precision in clinical practice. The use of Compas™ allows the prosthetist to see and understand alignment, and resultant imposed socket forces that previously could not be recognized. Research studies that further support the use of the Compas™ technology may be referenced in the letter.

Benefits to the Patient Through Using Compas™

1. Using the Compas™ instrumented Smart Pyramid™ will provide an optimal alignment that increases stability and control of the prosthesis, increasing safety during ambulation.
2. This optimal alignment decreases compensatory mechanisms during ambulation, decreasing energy expenditure, and greatly reducing the risk of co-morbidities.
3. An optimal alignment will also reduce the likelihood of socket related fitting issues and replacement sockets, which are often caused by improper alignment as a root cause.
4. A Compas™ aligned prosthesis results in decreased socket/interface stresses on the residual limb.
5. Using Compas™ objectively documents that the clinical care was performed appropriately.

Prosthetist Initial Evaluation Notes

Practitioner's initial evaluation notes should describe and justify specifically, the Smart Pyramid™ technology/platform and its benefits.

Why does the patient need a Smart Pyramid™ in their prosthesis? What is the benefit to the user? i.e. why is it difficult to align the prosthesis to the patient? Describe specific clinical issues such as bilateral amputations, short residual limb,

limb tissue sensitivity, etc. Describe specific prosthetic setup requirements. Describe the benefits of being able to document alignment related forces long-term for this patient. Finally, describe the patient's goals, and how the Smart Pyramid™ will enable the patient to reach those goals through better alignment.

Example only: (Use specific language for your particular patient. DO NOT copy verbatim)

...in order to optimize alignment and document the patient's gait pattern so that we can guarantee a more appropriate fit, more appropriate function, and reduce forces on the socket, the patient has been recommended for the use of a Smart Pyramid™.

The Smart Pyramid™ will provide outcome measures that will prove that we have achieved the optimal alignment for the patient at this time. The patient is a diabetic bilateral amputee with a short residual limb and a history of skin breakdown. Ensuring optimal alignment through the use of Smart Pyramid™ will reduce all pressures and forces on her residual limbs. Smart Pyramid™ will detect excessive pressures down the medial aspect of the limbs that if gone unnoticed, would lead to further skin breakdown. Due to the patient's medical history, all necessary steps need to be taken to ensure that the patient has a successful outcome and does not have continued breakdown on the residual limb.

The prosthesis will be fabricated as indicated. Attributed to a possible history of a mal-alignment on the prosthesis previously fabricated by a different company, the patient experiences very lax ligaments in the medial and lateral collateral ligaments of the knee. Therefore supracondylar suspension will be fabricated on the right side so that it is coming up slightly higher to ensure adequate ML stability at the knee

Other Key Documentation and Recommendations

- Make sure physician specifically describes the use of a Smart Pyramid™ in their prescription for the patient's prosthesis.
- Take pictures of use of the Smart Pyramid™ at fitting, including printouts of Compas graph results post final alignment, or pre and post clinical intervention – such as Compas™ graph with old ill-fitting socket, and with new well-fitting socket, or with broken prosthetic foot, and with repaired/replaced foot.
- Provide manufacturer product information including: Orthocare Innovations name and website, Manufacturers suggested retail price (\$2550), product name or part number, procedure code (L5999), copy of the [Smart Pyramid™ Brochure](#), and copy of Orthocare Innovations Smart Pyramid™ invoice, with specific component
- It is recommended to submit for reimbursement for the Smart Pyramid™

- the remainder of the clinical services is not held up by a potential denial of just the Smart Pyramid™.
- It is recommended to use an L5999 code and script language reading: Addition to lower extremity prosthesis, electronic force sensor component for optimization of dynamic alignment.
 - Copies of the Compas™ technical product summary, patient information summary, and alignment research summary can be found at [our website](#).

If Compas™ Instrumented Smart Pyramid™ Coverage is Denied

Until an L-code is established, coverage for the Compas™ instrumented Smart Pyramid™ may be denied for the initial submission. The more complete the initial documentation is however, the less likely it is that coverage will be denied.

If coverage is denied however, find out why the item was denied. Once determined, you can now address this specific reason in the appeal process. Possible reasons for denial may include:

- Not sufficient information: Make sure each of the above referenced documents have been submitted, and are written correctly. Even with the current L5999 coding, prosthetists are finding consistent success in getting Smart Pyramids™ covered by Medicare and Private Insurance alike. The key in achieving reimbursement on the Smart Pyramid™ is providing the necessary documentation as described above.
- Experimental or investigational: The development of the Compas™ system was supported by years of research from the National Institutes of Health, which established clear correlation between socket forces and prosthetic alignment. This scientific research confirms the clear benefits of using the Compas™ in clinical prosthetics use.
- Deluxe item: Find out what their definition of “deluxe” is, as well as how they define “standard” prosthetics. A typical definition of a “standard” prosthesis is: “the basic device(s) that have only the components essential to the functioning of the device and which return the individual to a functioning level.” The use of Compas™ provides better functional outcomes for patients by ensuring a measurable standard in quality of care.
- Medical Necessity: Be sure to address specific items missing in the Letter of Medical Necessity letter provided. See “Writing an Effective Letter” section above.
- Reasonable and necessary: This is defined by Medicare as the patient “reaching or maintaining a defined functional state within a reasonable period of time and is motivated to ambulate”. The use of Compas™ enables the patient to have greater stability, decreased inappropriate force distribution in the socket, and decreased energy expenditure during ambulation due to providing more optimized alignment and appropriate components.

- Least costly, most functional: This is often defined as the least costly alternative compared to another service/product that provides the same benefit. Compas™ allows the prosthetist to see and understand how to enhance the alignment in ways that are otherwise not possible. Alternative to using the Compas™ instrumented Smart Pyramid™ would be through extensive and expensive gait lab analysis.

