



GUIDE TO REIMBURSEMENT

CODING & BILLING OF THERATOOGS PRODUCTS

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DISCLAIMER

This guide is designed to offer basic information regarding reimbursement for TheraTogs, Inc. products.

Third party payment is influenced by many factors, not all of which can be anticipated or resolved by TheraTogs, Inc. The information contained in this guide was gathered from a variety of third party sources and is intended to provide general information only. TheraTogs, Inc. makes no statement, promise, express or implied warranty or guarantee (i) that the list of codes and narratives is complete or error-free, (ii) that the use of this information will prevent differences of opinions or disputes with payers, (iii) that these codes will be covered, or (iv) that the provider will be guaranteed reimbursement.

Readers of this document are advised that the contents of this manual are to be used as guidelines only and are not to be construed as policies of TheraTogs, Inc. TheraTogs, Inc. recommends this information be integrated with your payer guidelines, adjusting where necessary to meet the payer's billing requirements. This information is provided by TheraTogs, Inc. as a guide for coding TheraTogs products. It is not intended to increase or maximize reimbursement by any payer. This information is intended to assist providers in accurately obtaining coverage and reimbursement for their health care services. Providers assume full responsibility for all reimbursement decisions or actions. As with all procedures and services, you should: 1) perform the service or procedure; 2) document the service or procedure; 3) code the service, procedure and/or orthotic system or device; and 4) bill for the service, procedure, and/or orthotic system or device.

TheraTogs, Inc. assumes no responsibility for consequences attributable to or related to any use or interpretation of any information or views contained or not contained in this report. Each claim should be coded appropriately and supported with adequate documentation in the medical record. The codes listed are merely examples of codes, they are not necessarily correct coding.

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INTRODUCTION

TheraTogs, Inc. is pleased to provide you with this ***Reimbursement Guide to Coding and Billing of TheraTogs Products***. This guide is intended to provide our physicians, clinicians, suppliers and other interested parties (hereinafter referred to as “TheraTogs users”) with information designed to minimize reimbursement issues and facilitate appropriate claims submission. Addressing anticipated reimbursement issues proactively and efficiently will allow TheraTogs users to spend more time caring for clients and less time on reimbursement issues.

Specifically, this guide has been designed to:

- Provide general coding and coverage information on TheraTogs;
- Offer instruction on submission of properly documented claims;
- Provide a summary explanation of the preauthorization process (for non-Medicare claims).

This ***Reimbursement Guide***, designed for those TheraTogs users who are responsible for payer relations, coverage issues, preauthorization and billing, will be updated as coding and reimbursement issues are revised. Additional copies are available upon request.

Should you encounter any special billing or coding problems or have questions or concerns not addressed in this guide, we encourage you to contact TheraTogs at:
reimbursement@theratogs.com.

REIMBURSEMENT BASICS

There are hundreds of third-party payers in the United States, each with their own policies regarding coding, coverage and payment. This chapter provides an overview of these fundamental concepts.

CODING

Coding is a nomenclature system used by insurers and providers to identify diagnoses, procedures/services, and products. Codes also serve to track utilization and establish reimbursement rates for facility, professional services and products. The main coding systems that apply to TheraTogs products are ICD-9-CM diagnosis codes, CPT procedure codes, and HCPCS (Level II) codes. Examples of these codes are detailed in the following table:

Coding System Examples That May Apply To TheraTogs Products

Coding System	Used to Describe	Used By	Code Example/ Description
ICD-9-CM Diagnosis	The client's primary, secondary, etc. diagnosis that prompted the treatment and need for the TheraTogs product	<ul style="list-style-type: none"> • Hospitals • Physicians • Suppliers 	There are numerous ICD-9 diagnosis codes that may be applicable to TheraTogs products. Please consult the client's medical record and documentation for the most appropriate code.
CPT (Level I HCPCS)	<ul style="list-style-type: none"> • Professional service(s) 	<ul style="list-style-type: none"> • Physicians • Hospital Outpatient • Physical Therapists 	97760: Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes <i>Note: Clinicians may bill for the training & fitting of the orthosis using CPT code 97760 if the code used to describe the TheraTogs system does not include the phrase "includes fitting and adjustment".</i>
HCPCS (Level II)	Supplies, including TheraTogs products	<ul style="list-style-type: none"> • Physicians • Hospitals • Suppliers • Physical Therapists 	L1499: Spinal orthosis, not otherwise specified <i>Note: "T" codes are included in this guide but are not applicable to Medicare or commercial insurance payers. These codes are applicable to Medicaid only. Consult your payer for specific billing requirements.</i>

ICD-9-CM Diagnosis Codes

ICD-9-CM coding is a system used to describe the client's diagnosis that prompted treatment. All providers of care use ICD-9-CM *diagnosis* codes.

CPT/HCPCS Codes (Coding system applicable to TheraTogs products)

HCPCS (pronounced "hick-pics") is an acronym for Healthcare Common Procedural Coding System. There are two kinds of HCPCS codes:

Level I (CPT codes) used primarily to describe physician and ancillary care providers' professional services. CPT codes most specific TheraTogs would be CPT codes describing Orthotic and Prosthetic Management (CPT codes 97760 and 99762). See page 12 of this Guide for additional information.

Level II (HCPCS) used to describe supplies, drugs, DME products and orthotic devices and systems (such as TheraTogs products)

HCPCS Level II codes are nationally recognized by Medicare, many state Medicaid programs and most third-party payers. They are alphanumeric codes with alphabetic prefixes ranging from A-V. These codes supplement the CPT codes by providing specific descriptions for Durable Medical Equipment (DME) items and provider services not found within the CPT coding system. HCPCS Level II codes are used to describe:

- Orthotic devices, DME equipment, accessories, supplies, and repairs, prosthetics, medical and surgical supplies, etc.
- Medicaid specific codes (T codes)
- Temporary Medicare codes (usually Q or G codes)
- Other items and services such as medication, ambulance services, etc.

COVERAGE


Coverage is a term used by third-party payers to determine whether a product, service or procedure is eligible for reimbursement. Coverage policies will vary by payer and by plans offered by the same payer.

While numerous third-party payers model their coverage and reimbursement criteria based on Medicare guidelines, there are also many (such as Blue Cross Blue Shield) that have developed their own requirements in order to meet appropriate coverage criteria. Many of these plans contract with specific DME vendors and suppliers, and clients are required to obtain their DME from these specific vendors.

As healthcare costs continue to rise, many third-party payers have stopped covering certain DME items unless the employer purchases a special DME benefit rider. Basic DME coverage usually (but not always) includes lower cost items such as braces, crutches, splints, etc. Higher priced items, such as wheelchairs and hospital beds will usually require preauthorization before dispensing and will only be covered if the employer or patient has purchased a special DME benefit rider.

ü Medicare

- The basic definition of an orthosis (*a brace used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a diseased or injured part of the body*) must be met to establish eligibility for coverage.
- TheraTogs users should have a Medicare national supplier identification number to allow for billing of the item to the DMEPOS Medicare contractor (Medicare only).
- No special forms, such as Certificates of Medical Necessity (CMNs), are required.
- Evaluation of the patient and measurement and/or casting and fitting of the orthosis is included in the allowance for most orthotic products.
- Medicare requires the use of HCPCS codes when describing TheraTogs. For additional coding options, see your HCPCS coding manual or contact SADMERC (Statistical Analysis DME Regional Carrier) at: 877-735-1226 Monday through Friday 9:00 AM - 4:00 PM Eastern Time.



Important: SADMERC has an enhancement called the Durable Medical Equipment Coding System (DMECS), which is located on the SADMERC Web site, www.palmettogba.com. The DMECS allows the user to look up HCPCS codes and associated fee schedule(s). Future enhancements include a listing of SADMERC product classifications and a coding navigator tool that categorizes and combines HCPCS codes in a format that allows the supplier to easily determine how to code a product. To access the HCPCS codes and national fee schedule look up, go to: <http://www3.palmettogba.com/dmecs/jsp/index.jsp> and click on the “Search for Codes or Fees” box on the top left of the page.

ü Medicaid

- Medicaid coverage policies are state specific. While most agents recognize the medical necessity of the orthotic products, specific coverage guidelines will vary considerably between states. We recommend contacting your local Medicaid contractor for specific details on coverage.
- **Note:** We have included specific billing and coding instructions for California Children’s Services (CCS) on **page 15** of this guide

ü Third-Party Payers

- Due to the varying coverage policies of third-party payers, it is difficult to generalize coverage for orthotic devices. Not all health plans provide DME coverage and some employer groups must purchase a special DME rider to ensure coverage. We recommend that each third-party payer be contacted for its coverage guidelines for orthotic products.

ü Medical Savings Account (MSA)

- Many US employers offer medical savings accounts that allow an employee to contribute pretax dollars to a “savings account” that is used to offset noncovered medical expenses, copays, deductibles, etc. In absence of insurance reimbursement, TheraTogs products may qualify as a covered expense under an employee medical savings account.

PREAUTHORIZATION

PREAUTHORIZATION OVERVIEW

The most effective way to secure insurance benefits for your clients and avoid misunderstandings about financial liability is to preauthorize benefits prior to dispensing TheraTogs. Preauthorization is a process that allows physicians and other health care providers to determine, before treating a patient, if the procedure is eligible for coverage of a proposed treatment or service.

What is Preauthorization?

Preauthorization clarifies benefits and payment rates in advance, allowing you and your client to make informed decisions about TheraTogs. A preauthorization is never a guarantee of payment. Final determination will be subject to valid eligibility and applicable benefits at the time of rendered services.

The TheraTogs Clinical Sizing Kit provides you with the opportunity to preview the influence of the TheraTogs system on your client's status, and to photograph readily apparent improvements in posture, joint alignment, gait, balance, or limb function for the purpose of educating payers as to the medical need and effectiveness of an appropriate TheraTogs application.

In addition to clarifying insurance benefits, the preauthorization process is an excellent way to educate the payers about the unique features and benefits of TheraTogs. Many insurance companies require that services such as TheraTogs be preauthorized. Medicare is the exception; Medicare does not preauthorize services.

What is Precertification?

Precertification is usually required for hospital admissions, and clarifies in advance the expected length of stay, diagnosis and proposed treatment. Because TheraTogs systems are not typically supplied in the hospital inpatient setting, precertification will most likely not be required. However, we recommend that this requirement be clarified during the preauthorization process. In the rare instance that hospital admission is required, we recommend that the hospital admission be precertified in addition to preauthorized.

What is Predetermination of Benefits?

Many private payers no longer perform preauthorization of outpatient procedures. If the payer tells you preauthorization is not required, we recommend requesting a predetermination of benefits. A predetermination of benefits is a written request for verification of benefits. The request is based on policy provisions and allows an explanation of the client's potential benefits. A predetermination of benefits gives you and your patient a better idea of the client's anticipated out-of-pocket responsibility.

Dispensing a TheraTogs system may or may not require preauthorization. Due to variability among payers, we recommend that the payer be contacted *prior* to dispensing TheraTogs, to verify benefits and determine if a formal preauthorization is required.

Medical Necessity

Medical necessity must be established prior to any service or procedure being considered for coverage or payment. The same thing holds true for TheraTogs - medical necessity must be established in order for the service to be considered for reimbursement. If a TheraTogs system is presented as an “item of convenience” most payers will not cover it. Therefore, it will be important to establish the medical necessity of TheraTogs. Individual payers develop their own criteria for medical necessity. Payers should be consulted for their guidelines.

In support of your submission of medical necessity, we advise including comparative photographs or a videotaped record of the effects of the TheraTogs system on your client’s posture, mobility, or function.

In case of a non-coverage determination, the physician and/or physical therapist should have the patient sign a Waiver of Financial Liability in advance of services. The Waiver of Liability (see Appendix of this guide) ensures that the physician and the patient have a mutual understanding of payer reimbursement for TheraTogs and associated services as well as the client’s corresponding financial responsibility.

IMPORTANT!!

Some payers will refuse to perform preauthorization or predetermination of benefits but rather will review the claim for medical necessity upon submission of claim. If this is the case, strong supporting documentation must be submitted *with* the claim. This documentation should include a letter of medical necessity, clinical documentation – including comparative “before/after” photographs or video of TheraTogs’ effectiveness, invoice for TheraTogs and any other applicable information which supports the necessity of TheraTogs. In case of denial, an appeal letter should be submitted to the payer.

PREAUTHORIZATION PROCESS

Clinicians should inquire into the preauthorization process for all non-Medicare clients as soon as a candidate is identified. **Insurance carriers base their decisions on medical necessity as well as benefits, as outlined in the client’s certificate of coverage; therefore we encourage you to make a strong case for the client’s particular medical need for TheraTogs.** We do NOT recommend that clients or their family members preauthorize the procedure as they are probably not well equipped to answer the technical and/or clinical questions that the payer may ask. Furthermore, only the physician and/or therapist can adequately address the medical necessity for TheraTogs. If necessary, it is suitable to involve the patient in the appeal process.

Preauthorization Process

Once a candidate has been identified, and a Waiver of Financial Liability has been signed by the patient, a preauthorization or predetermination of benefits request should be submitted to the insurance carrier. Preauthorization may be performed via phone, letter, or fax. If you choose to preauthorize over the phone, documentation of the call is critical. The provider should document the date and time of the call, name of the person you spoke with, a brief summary of the phone call and the preauthorization number. Recently, some payers have started to preauthorize benefits “on-line” which may provide another option. The preauthorization letter should:

- Identify the client’s diagnosis and condition warranting TheraTogs (use the appropriate ICD-9-CM diagnosis codes).
- Emphasize the medical necessity of TheraTogs and lack of alternative treatment options.
- Brief narrative on how TheraTogs work (see page 13 of this Guide).
- Explain the clinical effectiveness of TheraTogs for your client. Use supporting photos and video if possible.
- Identify the intended supplier for TheraTogs.
- Identify all applicable codes and approximate charges as they apply to TheraTogs.
- Include additional information as requested by payer (clinical notes, treatment history, etc.)
- Additional information to consider: clinical publications, current bibliography, etc.

NOTE: One of the keys to communication with the payer is to establish the medical necessity for TheraTogs. Do not focus on “ease of use” or “item of convenience” for the patient or family. Medical necessity should be clearly established for coverage to be considered. A Sample Preauthorization Letter is included in this Chapter as an example of establishing medical necessity for your client.

PREAUTHORIZATION STEPS FOR THERATOGS

Step 1: Candidate identified for TheraTogs due to patient's medical necessity and unique benefits of TheraTogs

Step 2: Obtain copy of client's insurance card and all applicable patient and insurance information.

Step 3: In case of non-coverage decision, provider should have clients sign a Waiver of Financial Liability. See Appendix for sample form.

Step 4: Call the client's insurer to verify benefits and preauthorization requirements.* Ask for information specific to obtaining preauthorization such as telephone and fax number and where to send an overnight packet. Identify the payer's preferred method of preauthorization submission (fax or mail). Ask the payer to provide a list of materials required to obtain preauthorization, if possible.

Step 5: Prepare a preauthorization letter (also referred to as letter of medical necessity). A Preauthorization Sample Letter is included in this packet on page 9.

Step 6: Submit the letter and all supporting documentation and media (with appropriate codes) to the identified contact via fax or overnight delivery in accordance with the payer's directions (so that a return receipt can be obtained for tracking purposes).

Step 7: If you receive a letter confirming preauthorization, proceed with dispensing TheraTogs. If preauthorization is denied, begin the appeals process. (See Appeals Chapter of this guide.)



Step 8: Submit properly coded and documented claims.

Step 9: Track reimbursement; review EOB for appropriate coverage and payment levels.

Step 10: Appeal underpaid or denied claims as necessary. (See Appeals Chapter of this guide.)

*Some payers will refuse to perform preauthorization or predetermination of benefits but rather will review the claim for medical necessity upon submission of claim. If this is the case, strong supporting documentation must be submitted **with** the claim. This documentation should include a letter of medical necessity, clinical documentation – including supporting photos and/or video – the invoice for the TheraTogs system and any other applicable information which supports the necessity of TheraTogs. In case of denial, an appeal letter should be submitted to the payer (see Sample Appeal Letter in this Guide).

SAMPLE PREAUTHORIZATION LETTER

Re: Client:
Group #
Insured SS#:

This letter concerns my client, (insert client name), a (insert age and sex) who exhibits (or has been diagnosed with) (insert diagnosis). [Include statement of surgical history if applicable.] I am seeking a (preauthorization/predetermination of coverage) for my client for the use of a TheraTogs (insert TheraTogs System recommended) and hope the following information will be useful when making your decision.

As a result of (Insert client name)'s diagnosis of (restate diagnosis including primary and any secondary diagnoses) (s/he) currently demonstrates the following functional disabilities and risk factors:

- (insert all disabilities and risk factors applicable to the client's need for TheraTogs), which makes TheraTogs an appropriate treatment modality for this individual.

My client currently uses (insert applicable DME equipment or supplies currently used), but this equipment has failed to improve (his/her) condition. His/her current level of assistance is as follows: (indicate endurance level and dependency level for self care and mobility). I am recommending TheraTogs (insert name of TheraTogs System recommended) in particular as an appropriate treatment modality in the next step of (his/her) treatment. This TheraTogs product is specifically designed to meet (his/her) needs for (insert postural support or joint realignment needs). There are no commercially available products that can be customized to meet this particular client's need.

Include medical history, establish medical necessity; list modalities or strategies previously tried and note any lack of success.

I anticipate the following functional skills will be achieved with the use of TheraTogs (insert name of TheraTogs System recommended):

- (insert functional skills that can be achieved with proper support. Illustrate with video or photos if possible). *(NOTE TO CLINICIAN: Use GMFM –66 testing to identify functional gains and report them if possible)*.

I am sure you are aware of the potential for accelerated joint degeneration with chronic load-bearing joint malposition. Use of TheraTogs (insert name of TheraTogs System recommended) should avoid this complication. While I expect my client to require use of TheraTogs for (insert expected duration of equipment), another benefit of using TheraTogs is the growth adjustment offered by this device. I also anticipate the following physiologic benefits:

- (insert additional benefits such as musculoskeletal, GI, respiratory, etc).

Make a strong statement regarding the medical gains expected with use of TheraTogs. This portion of the letter must address medical or safety justification for the child, not ease for caregivers. Describe present dysfunction or future complications that can be reduced or resolved by using TheraTogs as extended therapy.



The following is a list of code(s) and estimated charges normally used for the TheraTogs product I am recommending.

TheraTogs Charges

Code	Description	Est. Charges
L1499	Spinal orthosis, not otherwise specified Note: Example only – see Coding Chapter for specific coding options	

I am sure you will agree that (Insert client name) meets all the criteria for TheraTogs and is an ideal candidate for use of the TheraTogs (insert name of TheraTogs System recommended). If you have further questions regarding this request for approval, please contact me at (insert).

Sincerely,

Cynthia Clinician, PT, MS
Contact Info

THERATOGS PRODUCTS AND REIMBURSEMENT

Product Overview

TheraTogs garments are designed to provide vertical stiffness to reinforce the wearer's postural alignment and stability, and horizontal extensibility to provide mild compression and a comfortable fit. The garments serve as a Velcro®-sensitive field for attaching elastic strapping (using Ultra Hook tabs) in virtually any configuration to provide orthotic support, to improve postural alignment, to enhance balance, or to enhance (or inhibit) specific movements. The straps resemble, and act as, external muscle. A properly fitted TheraTogs garment or component gives the wearer a comfortable, breathable, Latex-free "second skin" over his/her trunk and/or selected limb segments.

TheraTogs are designed to allow a clinician to send home with his/her client successful manual corrections achieved in therapy, in the form of an elasticized live-in system that continues to encourage improved posture, positioning, stability, or movement throughout the client's daily activities.

Product-specific reimbursement guidelines are available from the product pages of the company's website at www.theratogs.com.

TheraTogs Reimbursement

Reimbursement for TheraTogs - particularly under Medicare and/or Medicaid - is a common concern posed by TheraTogs users. Unfortunately, there is no single, specific answer to this question. The answer will vary depending on the state the TheraTogs user is in (Medicaid); the client's specific benefit policy (commercial insurance), and various other factors. TheraTogs, Inc. is working to find ways to improve the reimbursement environment for Medicare, Medicaid, early intervention programs, and commercial insurance (third-party) payers.

Overall, it is best to document the client's specific need(s) that the TheraTogs system addresses, supply a letter of medical necessity justifying the need and therapeutic treatment plan for the TheraTogs system, and any additional clinical data available (such as foot print and velocity studies, and pre- and post-application postural or functional assessment results).

Please note the specific billing requirements for California Children's Services (CCS) provided in this guide on page 15. TheraTogs, Inc. recommends supplying, at minimum, information similar to that requested by CCS to all insurance payers, in anticipation of future payer requirements.

CPT CODING FOR ORTHOTIC MANAGEMENT¹

Orthosis application differs from the purpose of an application of a cast or strapping device. Orthotics are used to support a weak or ineffective joint or muscle or they may be used to immobilize a part to facilitate a decrease in pain and inflammation. They may provide support while the patient transitions through treatment or they may be used permanently to facilitate movement or support a body part. Examples of orthotic devices include posterior leaf spring to facilitate ankle dorsiflexion after a cerebral vascular accident, shoe inserts for a patient with a pronated foot, or a static wrist orthotic for a patient with carpal tunnel syndrome.

Orthotic management codes include assessing the patient; determining the most appropriate orthotic, designing selecting and possibly fabricating the orthotic; and training in the use of the orthotic including wear time, skin care, and safety precautions. The patient's skin integrity, sensibility, and healing of tissues with or without surgical repair needs to be considered when determining the choice of materials, such as the type of thermoplastic or the use of pulleys and elastic tension. The code also includes the time associate with providing the patient instructions in exercises that are to be performed while the orthotic is in place.

The orthotic management codes are time based and intended to be reported once for each 15-minute increment. Materials and supplies may be reported separately with an appropriate supply or material code (eg, CPT code 99070 or HCPCS Level II codes). HCPCS L codes for orthotics include the evaluation and fitting component of the service. However, any training time associated with using the orthotic may be reported using 97760. The time reported must only be for time that the patient is present.

CPT Code 97760 includes additional orthotic management and training during follow-up visits including exercises performed in the orthotic, instruction in skin care and orthotic wearing time, and time associate with modification of the orthotic due to healing of tissues, change in edema, or interruption in skin integrity.

CPT code 97762 is intended for established patients who have already received the orthotic or prosthetic device. It is important for the health care practitioner to follow up with the patient after he or she has been provided with an orthotic or prosthetic device. The "checkout" visit would include assessment of the patient's response to wearing the orthotic or prosthetic device (such as possible skin irritation or breakdown); of whether the patient is donning the orthotic or prosthetic device appropriately; of the patient's need for padding, underwrap or socks; and of the patient's tolerance to any dynamic forces being applied. Code 97760 is appropriate to report if further training in the use of the orthotic or prosthetic device is required.

¹ CPT Assistant, February 2007, Volume 17, Issue 2

HOW THERATOGS WORK

TheraTogs employ the principle of applying prolonged, low-load (i.e. gentle), corrective forces to the musculoskeletal system - in functional context - in order to attempt to effect improvements in muscle recruitment strategies, and, with full-time use, in muscle physiology and in young bone geometry resulting from thousands of movements per day. The wearer gains the experience – and the training potential – of prolonged therapeutic “handling” throughout the day, every day, as s/he undertakes routine activities using TheraTogs-induced improvements in posture and joint alignment, and while recruiting underused muscles at more normal lengths.

The muscle groups most often targeted for TheraTogs strapping are underused and overlong. They are the synergists with or the antagonists to the muscles that are dominant in movement. For example, the gluteus medius and minimus muscles are often underused in the presence of a dominant group of hip adductors. So the hip abductors are shortened with TheraTogs strapping, and then put to work at a more appropriate length in daily function. If the tensor fascia lata (TFL) dominates as a hip flexor because of medial rotation of the knee axis in the swing phase of gait, then a lateral hip rotation strap is applied to move the TFL muscle force vector off the anterior hip joint, and to attempt to allow the iliopsoas to flex the hip more competently.

The basis for the TheraTogs strapping approach - that emphasizes shortening the long muscles before lengthening the short muscles, and that provides the user with a more effective movement or muscle activation strategy while working to gradually change the existing, pathological recruitment strategies - lies in the work of Shirley A Sahrman, PT, PHD, Professor in the Division of Physical Therapy at Washington University in St. Louis, Missouri.

The recommended sequence for selecting and applying strapping applications is the same that occurs in normal development, progressing from the sagittal to the frontal to the transverse-plane, paying close attention to the body-ground interface and how the child uses it as a base for engaging in activities. The work of Lois Bly provides a detailed guide to the building process that occurs in normal infancy. When in doubt, address upper trunk extension deficits first.

Each child or adult with CNS dysfunction presents hundreds of variables that comprise a unique constellation of sensory, motor, skeletal, joint, and muscular factors. TheraTogs, Inc. *strongly recommends* that all TheraTogs users undertake a full musculoskeletal assessment for each client prior to designing a TheraTogs strapping system, in order to identify problems of skeletal geometry, muscle imbalance, and joint laxity, and to exercise proper caution and safety in seeking correction of certain pathomechanical and pathokinesiological problems.

For example, two children with diplegic cerebral palsy might have achieved the same functional level, but they can demonstrate very different musculoskeletal characteristics. The same strapping application - say for reducing medial knee joint rotation in gait - might be appropriate for one but might risk the health of the hip joint in the other. Sensory perception might be very different, resulting in starkly different responses to wearing TheraTogs. One child might learn from them and wean out of them within 6 months. The other might only show improved function while wearing them, the way eye glasses improve vision only when worn. Or several years might be warranted to achieve a lasting learning effect. We do not know enough yet to determine who will fall into which group.

Once the assessment is completed, the clinical practitioner can use any combination of tension-generating force vectors and magnitudes to design a system of straps that persistently and gently manipulates the wearer's musculoskeletal system for as long as he/she wears it – and in some cases, after removing it. (This is what we mean when we say you can “send your hands home” with your patients.)

Generally speaking, a TheraTogs strapping system can replicate any light to moderate manual correction that the clinician can apply to improve a wearer's posture, balance, or limb motion. The complete system is typically introduced to the wearer in small stages over time, allowing him/her to adjust to the new demands of each strap, and allowing the caretakers to learn to apply the system correctly in stages.

The more severely-involved the client, the less obvious are the effects of TheraTogs wear. If manual correction of posture is heavy and difficult, TheraTogs have to struggle in a similar way. They are, after all, only fabric. The main benefits we've seen for client with severe involvement have been in their preference for wearing them, some relaxation or calming - either immediately or over time - and in easing the work load in carrying and positioning for their caretakers.

SPECIAL BILLING INSTRUCTIONS FOR CALIFORNIA CHILDREN'S SERVICES (CCS)

The following reimbursement coding and application guidelines, developed in accordance with from California Children's Services (CCS) requirements, should be used when seeking reimbursement for TheraTogs from CCS.

APPLICATION GUIDELINES

- To be considered by CCS for reimbursement, the TheraTogs system must be provided by an approved Orthotic and Prosthetic supplier who is registered to provide services through the State of California Medi-Cal program.
- Due to their orthotic effect and biomechanical impact, TheraTogs are considered to be an Orthotic appliance.
- Under the CCS guidelines, TheraTogs will be reimbursed **"By Report,"** which requires the following to be submitted when billing for a patient:
 - ü Use HCPCS Code L1499 (Spinal orthosis, not otherwise specified) for the base TheraTogs garment system
 - ü Include item description
 - ü Manufacturer's name: TheraTogs, Inc.
 - ü Model number
 - ü Catalog number
 - ü Suggested retail price
 - ü Medical condition necessitating TheraTogs
 - ü Physician's prescription and medical justification

Note: In anticipation of future payer requirements, TheraTogs recommends supplying, at a *minimum*, documentation similar to that requested by CCS to all insurance payers.

CLAIM SUBMISSION AND DOCUMENTATION

Submitting properly coded and documented claims is critical to reimbursement. This section provides generally accepted guidelines regarding claims and documentation.

Medicare

Many federal and state regulations require that a physician order the DME item, complete specific portions of the paperwork and maintain the client's records. Written documentation is critical in order for payment to be made for DME items. The following documentation is necessary for DME items regardless of the payer:¹

- The clinician should sign and date an order for the DME item
- The supplier must keep the order on file
- If the treating provider is also supplying the item, the clinical notes should substantiate the need for the item
- The diagnosis establishing the medical necessity for the item must be documented in the medical record
- If the payer determines that medical necessity has not been established, the patient must sign a waiver before receiving the item.

To meet the requirements of medical necessity for all health care services reported to the Medicare program and third-party payers, the client's medical record must reflect the nature and extent of the diagnosis or injury. Clear documentation should be consistently maintained for all payer types and contain the following patient-specific information:

- Physical examination findings
- Diagnostic tests/analyses results
- Relation of diagnosis to the DME items
- Complicating co-morbidities
- Physical functional abilities and/or limitation
- Duration of the diagnosis
- Overall expected course of treatment/prognosis
- Rehabilitation potentials

In addition to the criteria listed above, an appropriate patient history must be obtained.

For DME items or services to be billed, the physician or therapist must have documentation demonstrating the medical necessity of the item. This information must be part of the client's

¹ 2006 Coders' Desk Reference, HCPCS Level II, ©2005 Ingenix, Inc.

medical record. For suppliers of DME items, an official order signed and dated by the ordering provider must be obtained. The order must detail the following:

- The client's identifying information
- A description of the DME item
- The reason for the DME prescription, which can be in the form of ICD-9-CM code(s) and/or diagnosis narrative information.

The provider's signature must be an original signature. A faxed copy of the original order temporarily satisfies the requirement for most payers and allows the supplier to begin filling the DME order. However, the supplier must obtain the original document from the provider as soon as possible. The supplier then keeps the original DME order on file. A copy of the order must be sent to Medicare or third-party payer when requested.

Providers may receive requests from DME suppliers for copies of patient records which supports medical necessity of the provider's order. This request is usually in response to a direct request made to the supplier from Medicare or the third-party payer for purposes of verifying the need for the DME item(s). Suppliers are responsible for ensuring that coverage criteria is met before providing an item, or they run the risk of having their claim rejected. This is a CMS directive to all DME suppliers and is routinely reviewed during supplier audits.

Notes:

A supplier of orthotic devices must be enrolled in the Medicare program as a DMEPOS Medicare contractor in order to bill Medicare for services rendered.

Submission and payment of claims for the orthotic device is based on the site of service (e.g. hospital) where the patient resides (for DMEPOS Medicare contractor). Medicaid and private payers should be contacted for their specific requirements.

For purposes of this guide, it is important to note that Medicare does not require a Certificate of Medical Necessity for orthotic devices.

Medicaid

Most Medicaid state agencies follow Medicare guidelines and documentation requirements. Clear and consistent documentation is necessary, regardless of the payer. Review the Medicare guidelines above for the required detailed documentation. We recommend contacting your local state agency to determine if additional or special documentation required.

Third-Party Payers

To meet the requirements of medical necessity for all health care services reported to third-party payers, the client's medical record must reflect the nature and extent of the diagnosis or injury. Clear documentation should be consistently maintained for all payer types and contain the following patient-specific information:

- Physical examination findings
- Diagnostic tests/analyses results
- Relation of diagnosis to the DME items
- Complicating comorbidities
- Physical functional abilities and/or limitation
- Duration of the diagnosis
- Overall expected course of treatment/prognosis
- Rehabilitation potentials

In addition to the criteria listed above, an appropriate patient history must be obtained.

Clean Claims

Clean claims are those claims that are submitted to third-party payers accurately reflecting all the necessary information for processing. Clean claims are usually paid in a timely manner. Below is a list of common errors that may cause delays in claims processing:

- Patient's ID number is incorrect.
- Patient's full name and address does not match the insurer's records.
- The client's information is incomplete.
- The physician's identifying information (for example, Tax ID number) is missing.
- The physician's signature is missing.
- Dates of service are incomplete or do not match the associated claim history for the patient.
- Charges are omitted.
- Invalid CPT and/or ICD-9 codes are used.
- Information on the claim form is illegible.

CLAIM FILING INSTRUCTIONS

Providers' services and their corresponding charges are reported on approved claim forms. Claim forms are relatively universal and are accepted by most insurance carriers. Hospitals submit claims using the UB-04 claim form (for inpatient and outpatient services) or electronic equivalent. Physicians, therapists, suppliers, etc. use the CMS-1500 or its electronic equivalent.

Since TheraTogs will most likely not be dispensed in the hospital inpatient or outpatient setting, we have included claim instructions and examples for the CMS-1500 only. If guidance for billing in the hospital inpatient or outpatient setting is required, please contact TheraTogs.

Provider insurance claims are submitted in two ways: 1) electronically or 2) manually. Most claims are processed electronically. Certain small physician office groups, defined as having fewer than 25 full time employees or physicians with fewer than 10 full time employees, are exempt from electronic claims filing requirements. Most physician practices are equipped to submit claims both ways because claims that require extensive documentation must still be filed manually. Private payers should be contacted for their submission guidelines and policies.

Advantages of electronic claims filing:

Because of the automated process, electronic claims are usually processed more quickly than paper claims. For example, Medicare is mandated to process electronic claims within 14 days, while the paper claims threshold is 27 days. Electronic claims are also less likely to be rejected by payers. Most electronic claims processing software contains claim-editing features that detect and report incomplete claims, invalid codes and other problems that will cause the claim to be rejected. Furthermore, electronic claims cost less to process providing incentives for third party payers to discourage manual claims filing.

CLAIM INSTRUCTIONS

Services for TheraTogs should be reported on the CMS-1500 claim form or its electronic equivalent. For a complete list of coding options, consult your current ICD-9-CM and CPT manuals.

The coding provided below is a sample only. TheraTogs users should code and bill for their services based on services performed.

Note: The *CMS-1500 claim form* is being revised to accommodate the reporting of the National Provider Identifier (NPI). There are currently two versions of the *Form CMS-1500*. **The Form CMS-1500 (08-05) version was effective October 1, 2006, but will not be mandated for use until June 1, 2007 at the earliest.** Because of the NPI dual usage period, there will be overlap between the use of the old and the new Form CMS-1500.

We have included the revised form on the following page as a Claim Form example.

CMS 1500 CLAIMS FORM FIELD	GUIDELINES/COMMENTS
Field 21 (Diagnosis code)	
Diagnosis code example: 340 Multiple sclerosis	Report appropriate diagnosis code in this field. For a comprehensive list of coding options, consult your ICD-9-CM manual.
Field 23 (Prior authorization field)	
Enter appropriate prior authorization or precertification number (if supplied)	
Field 24B (Place of Service)	
An appropriate code might be: 49 (Independent Clinic)	Enter appropriate place of service (where procedure/service was performed).
Field 24D (CPT/HCPCS - procedures, services or supplies)	
HCPCS code example: L1499 Spinal orthosis, not otherwise specified	Code all applicable procedures, services and supplies in accordance with coding guidelines. For a complete list of coding options, consult your CPT/HCPCS manual.
Field 24J (National Provider Identifier Number (NPI))	
Enter TheraTogs user's assigned NPI number	

SAMPLE CMS 1500 PAPER CLAIM FORM

1. MEDICARE <input checked="" type="checkbox"/> (Member of) MEDICAID <input type="checkbox"/> (Member of) TRICARE <input type="checkbox"/> (Spouse's/Service Member's) C-IMPVA <input type="checkbox"/> (Member of) GROUP HEALTH PLAN <input type="checkbox"/> (SSN or ID) FECA <input type="checkbox"/> (SSN) OTHER <input type="checkbox"/> (ID)				1a. INSURED'S ID NUMBER (For Program in Item 1)			
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Jones, John J.				3. PATIENT'S BIRTH DATE (MM DD YY) 09 19 1931 SEX <input checked="" type="checkbox"/> M <input type="checkbox"/> F		4. INSURED'S NAME (Last Name, First Name, Middle Initial)	
5. PATIENT'S ADDRESS (No. Street) 1234 Any Street				6. PATIENT RELATIONSHIP TO INSURED Self <input checked="" type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		7. INSURED'S ADDRESS (No. Street)	
CITY Anywhere STATE USA		8. PATIENT STATUS Single <input type="checkbox"/> Married <input checked="" type="checkbox"/> Other <input type="checkbox"/>		CITY		STATE	
ZIP CODE 99999 TELEPHONE (Include Area Code) (999) 999-9999		9. EMPLOYMENT? (Current or Previous) Employed <input type="checkbox"/> Full-time <input type="checkbox"/> Part-time <input type="checkbox"/> Student <input type="checkbox"/>		ZIP CODE		TELEPHONE (Include Area Code)	
6. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)				10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> PLACE (State) _____ c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>			
a. OTHER INSURED'S POLICY OR GROUP NUMBER				11. RESERVED FOR LOCAL USE			
b. OTHER INSURED'S DATE OF BIRTH (MM DD YY) SEX M <input type="checkbox"/> F <input type="checkbox"/>				12. RESERVED FOR LOCAL USE			
c. EMPLOYER'S NAME OR SCHOOL NAME				13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)			
d. INSURANCE PLAN NAME OR PROGRAM NAME				SIGNED _____ DATE _____			

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM. AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to request payment of government benefits either to myself or to the party who accepts assignment)											
15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS, GIVE FIRST DATE (MM DD YY)											
16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM MM DD YY TO MM DD YY)											
17a. ICD-9-CM diagnosis code(s) 340											
17b. NPI											
19. RESERVED FOR LOCAL USE											
21. DIAGNOSIS OR NATURE OF ILLNESS (Use 1, 2, 3 or 4 to Item 24E by Line)											
22. MEDICAID RESUBMISSION CODE											
23. PRIOR AUTHORIZATION NUMBER ZZZYYY1234567											
24. A. DATE(S) OF SERVICE (From MM DD YY To MM DD YY)		B. PLACE OF SERVICE		C. EMG		D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) (CPT/HCPCS MODIFIER)		E. DIAGNOSIS POINTER		F. \$ CHARGES	
04 01 07 04 01 07 49		L1499		49		1		\$\$\$.\$\$		1	
04 01 07 04 01 07 49		XXXXX		49		1		\$\$\$.\$\$		1	
25. FEDERAL TAX ID NUMBER (SSN EIN)											
26. PATIENT'S ACCOUNT NO.											
27. ACCEPT ASSIGNMENT? (For govt. contracts, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>											
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)											
SIGNED _____ DATE _____											

NOTE: SAMPLE ONLY – THERATOGS USERS SHOULD CODE AND BILL FOR SPECIFIC SERVICES PROVIDED. THE CODES LISTED BELOW ARE EXAMPLES ONLY FOR THE PURPOSE OF ILLUSTRATION.

Field 21:
Enter appropriate ICD-9-CM diagnosis code(s)

Field 24B:
Enter appropriate code indicating where service was provided

Field 23:
Enter preauthorization number if available

Field 24G:
Enter appropriate number of units for each service provided

Field 24D:
Enter appropriate codes for applicable services, procedure and supplies. Include appropriate documentation where necessary

Field 24E:
Enter diagnosis code(s) corresponding with code(s) in Field 21

Field 24F:
Enter appropriate charges for each service/supply provided

Field 24J:
Enter Medicare Provider ID # and National Provider ID # (NPI), if applicable

Enter provider information including provider number or other identifying information

**Therapy Specialists
999-9999999
999 Main Street
Anywhere, USA 99999
XXX999**

This information is provided by TheraTogs, Inc. as a guide for coding services involving TheraTogs products and is not intended to increase or maximize reimbursement by any payer. Proper coding does not ensure coverage or payment any payer. Third-party payers should be consulted in regard to local coverage, coding and reimbursement policies. It is the provider's responsibility to verify coverage and submit the necessary documentation. Providers assume full responsibility for all reimbursement decisions or actions.

SAMPLE ELECTRONIC CLAIM FORM

While there are multiple screens and fields involved in completing the electronic claim form, the following illustration highlights pertinent coding for the Professional Claim Form Line Item Details.

Professional Claim Form

Patient Info & General | Insured Information | Billing Line Items | Extended Patient/General | Extended Payer/Insured

Line Item Details | Extended

Enter all applicable diagnosis code(s) resulting in a line item service.

Claim Diagnosis Codes: 1 2 3 4 5 6 7 8

LN	24a - Service Dates From Thru	24b PS	24c TS	24d Proc	24d - Modifiers 1 2	24e Diagnosis	24f Charges	24g Units	EP	FP	EM	CB	AT	Rendering Physician
1	0401 07 04 01 07	49		L1499		340	\$\$\$.\$	1.						9999999
2	0401 07 04 01 07	49		XXXXX		340	\$\$\$.\$	1.						9999999
3														
4														

24a: Enter date(s) of service.

24b: Enter place of service code identifying where the service was performed

24d: Enter HCPCS/CPT code for each line item service provided (include applicable modifiers).

24e: Enter primary diagnosis code corresponding with each line item service provided.

24f: Enter appropriate charges for each line item service provided.

24g: Enter corresponding number of units for each line item service provided.

APPEALS

All payers, including Medicare, Medicaid, and third-party payers, have an appeal process of some kind in accordance with state and federal laws. This Chapter describes the Medicare appeals process. State Medicaid agencies and individual third-party payers should be contacted for their specific appeals process.

If you learn that coverage/payment for your client will most likely be denied, you should request that the client sign a *Waiver of Financial Liability*. The Waiver of Liability (sample included in the Appendix of this guide) ensures that the TheraTogs user and client have a mutual understanding of a lack of private payer reimbursement for the procedure and associated services as well as the client's corresponding financial responsibility.

Medicare

The Medicare program offers suppliers accepting assignment and beneficiaries the right to appeal claim determinations made by the carrier. The purpose of the appeals process is to ensure the correct adjudication of claims. The appeals activities conducted by carriers are governed by instructions from the CMS. Suppliers who provide services to Medicare Part B beneficiaries may appeal an initial claim reimbursement determination. Beneficiaries also have the right to appeal any claim determination.

The time limit for filing either a review request or a hearing request is six months from the date of the previous determination notice. The time limit may be extended only if good cause for late filing is established.

Telephone Reviews

Review of claim decisions may be conducted by either telephone or correspondence. The telephone review is the most efficient method for both parties. The two-way conversation allows information to be more easily exchanged and questions to receive immediate response. If a supplier does not agree with the first claim decision, he/she may call and ask the DMEPOS Medicare contractor to take a second to look at the claim. The supplier must present a clear reason for requesting a review and be able to provide the additional information required to revise a decision at the time of the call. Examples of items that can be addressed by telephone are:

- Number of services/units required
- UPIN number for ordering physician
- Itemization of charges required
- Claim detail line correction
- Submitted charges not processed on initial claim
- Date of service correction
- HCPCS coding corrections
- Claim processed under incorrect health insurance claim number

- Claims incorrectly denied as duplicates
- Diagnosis reference missing from the original claim
- Diagnosis code(s) not given on the original claim

Suppliers who do not accept assignment on a claim may call for an appeal. However, because of privacy act information laws, the decision will be mailed to the beneficiary. An exception may be made if the caller can provide a copy of a beneficiary authorization for release of information by fax.

The supplier may request a telephone review on any issue. However, the DMEPOS Medicare contractor reserves the right to request a written review be submitted on complicated issues. The DMEPOS Medicare contractor may also ask the supplier to fax certain information before a decision can be made. In some cases, referral to the DMEPOS Medicare contractor medical staff may be necessary for an accurate decision and an immediate decision cannot be made. When this occurs, the DMEPOS Medicare contractor will notify the supplier of the decision in writing or by calling with the reply.

All medical information provided to the DMEPOS Medicare contractor must be documented in the client's file and available to the DMEPOS Medicare contractor should an audit be required.

The supplier may request a review within 6 months from the initial claim decision. A review by telephone cannot be requested if Medicare has previously issued a written review decision. If a previous review decision has been issued, a Fair Hearing request must be made in writing. General questions and requests for claims status cannot be handled by this process. These issues must be handled through the normal Provider Assistance telephone service.

Reasons for Claim Reversals

According to Medicare, the following were listed as the top reasons claims were reversed at the appeal level:

- In 45% of the cases reversed, additional information, more detailed documentation of the client's condition, or proper diagnosis coding was supplied at the appeal level.
- In 18% of the cases reversed, a Unique Physician Identification Number (UPIN) was submitted or corrected at the appeal level.
- In 18% of the cases reversed, a request for modifier change or addition to the claim was requested.

To avoid the frustration of claim denials and appeal processing, we suggest checking to be sure that the claim form contains all the required information. Claim submitters should verify that the correct UPIN number, modifier, procedure code and diagnosis have been indicated on the claim.

Incomplete or insufficient documentation of a client's medical condition could result in claim denial.

For more information on additional level of Medicare appeals, please consult your Medicare supplier's manual.

Third-Party Payers

There are many commercial health insurance plans available in the marketplace today. However, coverage policies and more importantly, benefit plans, are as diverse as the health care insurance business, making it difficult to accurately predict what the details of coverage are. It is important to understand that while a payer may have a coverage policy in place for products such as TheraTogs, all policies are subject to benefit exclusions which will override a coverage policy.

If the preauthorization/predetermination request or claim for TheraTogs is denied, the first step is to determine *why* it was denied. Ask for the denial in writing. Appeals are more effective when prepared in direct response to the specific denial reason.

Some payers may reject payment due to a lack of knowledge and understanding of TheraTogs while others may deny payment due to benefit exclusions DME or lack of medical necessity. While it is important to appeal these decisions, we recommend that each TheraTogs candidate's insurance policy be investigated through the preauthorization process to identify specific coverage terms and limitations.

The most common reason for denial of benefits for TheraTogs will be "*excluded from coverage policy*" or "*not medically necessary*". If this is the case, we recommend appealing immediately. **The appeal should clearly distinguish the medical necessity and medical benefit of using TheraTogs.** Contact the Medical Director at the insurance company to discuss this case specifically and to further explain the medical need for TheraTogs.

We have included a Sample Appeal Letter and a Supplemental Appeal Letter (to address medical necessity) on the following pages. These letters may be modified to include other reasons for denial.

SAMPLE APPEAL LETTER

Re: Patient:
Subscriber:
Group #:
Insured SS#:

I am writing to appeal your decision to deny benefits to my patient, (insert patient name) for the TheraTogs (insert TheraTogs System recommended). The basis for your denial (attach copy of denial letter) indicates that TheraTogs is not a covered item because it is (insert appropriate denial reason such as: excluded from my client's benefit policy; not medically necessary, etc.) Apparently there is a misunderstanding about the nature of the TheraTogs product, which I hope can be clarified with the following information.

NOTE TO CLINICIAN: CONSIDER ANY OF THE FOLLOWING, AS APPROPRIATE BASED ON THE REASON FOR DENIAL OF COVERAGE --

Ø TheraTogs is not medically necessary.

- The denial is usually based on the client's medical history. It is critical that sufficient medical history be provided or established for the insurance company to consider coverage of TheraTogs. Send an appeal letter that details the client's medical history, treatments tried and failed and the importance of TheraTogs to the client's functional skills and the physiologic benefits. Also include a statement that there are no alternative treatments for your patient.
- **For suggested appeal letter based on medical necessity, see next page .**

Ø Orthoses or orthotic devices are specifically excluded by the plan.

- This statement will be the most difficult to resolve if there is a *specific* non-coverage statement for orthosis. If this is the reason for denial, the client's medical policy or benefits handbook should be reviewed carefully to locate the paragraph *specifically* excluding orthosis.
- If orthosis *are* specifically excluded, we recommend involving the patient by having them appeal the denial through their employer. Many insurance plans are "self-funded" meaning the employer has discretion over the administration/benefit coverage for their employees. Some denials may be overturned based on the employer's intervention.

I would appreciate your immediate response to this matter. (Insert patient name) has been extremely distressed over the prospect that (his/her) insurance will not cover TheraTogs (insert TheraTogs System recommended) and that (his/her) right to the physiologic benefits as well as the functional improvements offered by TheraTogs is being denied. Please contact me immediately with any further questions you may have concerning this appeal.

Sincerely,
Thomas Clinician, PT

SUPPLEMENTAL SAMPLE APPEAL LETTER – MEDICAL NECESSITY

Re: Client:
Birth Date:

Diagnosis:
Relevant medical/surgical history:

Parent/Guardian (if applicable):
Group #
Insured SS#:

I am seeking (preauthorization / predetermination of coverage), on behalf of (insert client name), for the provision of a TheraTogs (insert TheraTogs System recommended), and hope that the following information will be useful when making your decision.

TheraTogs undergarment and strapping systems are designed to provide the wearer with day-long carry-over and functional practice of successes in postural and joint alignment achieved during a therapy session. New studies on neuromotor re-education emphasize the need for practice – literally thousands of repetitions - to acquire new skills. To gain optimum posture and function, therefore, thousands of repetitions of movements must occur in optimum alignment. TheraTogs accomplish this objective with specialized, elastic fabrics that foster active rather than passive correction. Please refer to Table 1 on page 3 of this document for a review of (client's name's) current impairments, functional deficits, risk factors, rehabilitation goals, and rationale for this request.

My client currently uses (insert applicable DME equipment or supplies), that contribute(s) to (my client's) welfare by (explain benefits to support their previous funding), but which has failed to meet (his/her/the family's/my) rehabilitation goals. On the basis of the results observed in the clinical trial that we undertook using a TheraTogs clinical sizing kit, I am requesting TheraTogs (insert name of TheraTogs System recommended) ___ as an appropriate treatment modality in the next step of (his/her) rehabilitation program.

List modalities or strategies previously tried and note any lack of success.

TheraTogs were designed to address problems of posture and movement that are multifactorial and complex. The attending clinician identifies key issues and supervises the use of corrective strapping. No other commercially available products satisfy the objectives of effecting immediate, problem-specific improvement in all-day posture and joint alignment with essential adaptability to support treatment goals.

Supporting Clinical Data:

(NOTE: Use comparative GMFM –66, footprint studies, gait velocity, hand use, or ADL testing to identify gains observed during the TheraTogs trial, and report them here.) (Client's name) is expected to experience the following physiologic benefits: (Insert additional benefits such as musculoskeletal, GI, respiratory, nutrition, etc).

Strong statement should be made regarding gains observed (comparative data is your strongest argument) and expected with TheraTogs. This portion of the letter must address medical and/or safety justification for the client, not ease for caregivers.

APPEALS
SUPPLEMENTAL APPEAL LETTER (MED NECESSITY)

I anticipate that my client will require the use of TheraTogs for (*insert expected frequency and duration of use*). TheraTogs systems provide for some growth adjustments.

The following is a list of code(s) and typical cost of the TheraTogs product I am recommending.

TheraTogs Charges

Code	Description	Est. Cost
L1499	Spinal orthosis, not otherwise specified Note: Example only – see Coding Chapter for specific coding options	





I am sure you will agree that (Insert client name) is an ideal candidate for use of the TheraTogs (insert name of TheraTogs System recommended). If you have further questions regarding this request for preauthorization, please contact me at (insert).

Sincerely,

Cynthia Clinician, PT
(Contact Info)

TABLE 1

The following is an example of patient specific clinical information to consider including in the Appeal Letter to justify the medical necessity of TheraTogs.

Client: WS Age: Diagnosis: Right Brachial Plexus Injury at birth				
(WS) currently demonstrates the following functional disabilities and risk factors, for which short and long-terms goals have been developed.				
IMPAIRMENTS	FUNCTIONAL DEFICITS	RISK FACTORS IF UNATTENDED	SHORT TERM REHABILITATION GOALS	LONG-TERM REHABILITATION GOALS
Weak right shoulder muscles	Limited independence in age-appropriate self-care skills requiring 2 hands.	Premature degeneration of malaligned joints.	Assist weak muscles and improve functional shoulder and elbow alignment throughout the day using TheraTogs (see below). Improve alignment to optimize performance during strengthening exercises using TheraTogs.	Re-educate the neuromusculo-skeletal system to retain improved shoulder and forearm alignment, strength, and functional use.
Weak right elbow and forearm muscles.	Overuse of unaffected hand. Poor self esteem.	Overuse and premature degeneration of the left shoulder and arm.	Protect shoulder and arm joints from deforming strains during sleep using TheraTogs.	
Compensatory pelvic obliquity with potential spinal scoliosis.	Attempts to raise the right arm result in trunk deviations that persist into daily life.	Back pain, hip pain in early adulthood.	Restore optimum postural alignment throughout the day, using the TheraTogs BPI Rehab Support System (see below).	Re-educate the neuromusculo-skeletal system to retain improved postural alignment.
		References are available upon request for evidence of long-term effects of chronic, functional joint malalignments and muscle imbalances.		

Research Studies on TheraTogs

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FREQUENTLY ASKED QUESTIONS

The following is a list of questions designed to assist the reader in understanding the most frequently asked questions pertaining to TheraTogs products.

1. Q. What is a HCPCS code?

A HCPCS code is a Level II code used to identify durable medical equipment, prosthetics, orthotic devices and/or supplies being billed. HCPCS Level II codes are recognized by Medicare, most Medicaid agencies and third-party payers.

2. Q. Who is responsible for correct HCPCS code identification of the product?

The provider is responsible for using the appropriate HCPCS code. However, in addition to this Reimbursement Guide, SADMERC (Statistical Analysis DME Regional Carrier) can be contacted for coding help on all DME products. SADMERC is specific to Medicare and can be contacted at 877-735-1326 (9:00 AM - 4:00 PM EST).

3. Q. Do private payers follow SADMERC coding recommendations?

Yes. Recommendations are usually adhered to by state Medicaid agencies, workers compensation agencies, and third-party payers.

4. Q. What type of calls are referred to the DMEPOS Medicare contractors?

The type of calls referred to the DMEPOS Medicare contractors include: coverage and utilization questions; eligibility; claim inquiries; claims forms; documentation requirements; allowables for items priced by reasonable charge and individually considered items; publications, such as the Supplier Manual, Advisories and Fee Schedule Catalogs, CMN Information; and Type of Service and Place of Service codes.

5. Q. We are a supplier in a state that is different from where the patient resides. Which DMEPOS Medicare contractor do we bill for our Medicare client's services?

Claims for DMEPOS Medicare contractors are adjudicated based on the *residence of the patient*, not the place of service where the DME was furnished. Suppliers should obtain the client's permanent address (place of residence where the patient spends more than six months of the calendar year) and submit the claim to the appropriate DMEPOS Medicare contractor. A list of the DMEPOS Medicare contractors, can be downloaded from the CMS website at: http://www.cms.hhs.gov/DMEPOSFeeSched/Downloads/DMERC_and_DME_MAC_Contacts.pdf

6. Q. Why do some of our clients have coverage for orthotic devices and others do not?

Not all health plans provide DME coverage and some employer groups must purchase a special DME rider to ensure coverage. Due to the varying coverage policies of third-party payers, it is difficult to generalize the coverage policies for orthotic devices. We recommend that each third-party payer be contacted for their specific coverage guidelines.

7. Q. Is TheraTogs covered by Medicare, Medicaid or commercial insurance?

Some insurance companies, including Medicare and Medicaid pay for TheraTogs. However, the coverage will depend on each client's insurance benefit package as well as medical necessity. Start the process by reviewing the client's insurance benefits to better understand their specific coverage for orthotic devices or durable medical equipment. It is always best to check with the insurance company about coverage issues before purchases are made; this will avoid unexpected out of pocket expenses. In addition, your insurance company will inform you of criteria needed for claims filing.

8. Q. Will TheraTogs, Inc. bill my insurance company?

No. TheraTogs, Inc. is the manufacturer of TheraTogs, not a provider of healthcare services. Therefore, you or your provider of service (medical clinician) is responsible for billing the insurance company.

9. Q. What code do I use to bill TheraTogs?

TheraTogs are designed for individual use in a variety of applications in support of a wide range of therapeutic results and objectives. As a result, there is not one code pertinent to all claims. Further, your claim may require two or more billing codes. First, find out what type of code your insurance company requires. In most cases, refer to the "L" code category to determine which limb or extremity code best fits your circumstance.

10. Q. What is the reimbursement rate for TheraTogs?

We cannot guarantee the amount of your reimbursement, if any. The reimbursement rate will depend on the insurance company, the healthcare provider's contractual obligations with the payer, and the insured's payable benefits. We recommend contacting the payer for specific reimbursement rates.

11. Q. Does a prescription have to accompany the TheraTogs order form?

It depends. TheraTogs have been registered with the FDA (Food and Drug Administration) as a Class I (Exempt) Medical Device. TheraTogs Systems are intended to be applied under the supervision of a licensed, healthcare practitioner. A clinician's prescription is required if you place your order through the Research Partner Program at TheraTogs, Inc., however, your clinician may also order through our Providers or catalog-based Distributors, generally without a prescription.

12. Q. I understand TheraTogs is classified as a Class I medical device – what does that mean?

Class I devices are subject to the least regulatory control because they present a minimum of potential for harm to the user. TheraTogs were determined to be a Class I (Exempt) device as they are worn on the outside of the body and have negligible potential for harm. Examples of other Class I Devices are ankle orthoses, foot orthoses, knee braces, etc.

13. Q. Do I have to purchase TheraTogs from a medical supply company?

You don't *have* to, necessarily. The policy of the payer - typically the client's insurance company (including Medicare/Medicaid) - will determine the source from which TheraTogs should be purchased. For instance, if an insurance company or a state's early intervention program requires the "supplier/provider" to bill supplies directly to them, the clinician may order them through an approved Supplier/Provider (such as a local O&P clinic) that has a Provider account with TheraTogs, Inc. Clinicians who do not require reimbursement billing through an approved Provider should check our website at www.theratogs.com for ordering alternatives.

14. Q. My insurance company says they have never heard of TheraTogs. How do I explain what a "TheraTogs" is to my insurance company?

"TheraTogs" is a brand name. When inquiring about a client's insurance benefits, it should be explained how the product will be used and the benefit to the patient. TheraTogs should be described as an **orthotic garment and strapping system**. Other general terms to describe TheraTogs are:

- bracing
- splinting
- hip, spinal, knee, ankle orthosis.

15. Q. My insurance company will not consider coverage for TheraTogs unless I can show medical necessity. How can I get them to best understand the need for TheraTogs?

The client's medical history, medical services provided and time spent is documented should be documented in the client's medical chart each time there is an encounter with the clinician. The clinician should extract the data from the chart to develop what is commonly known as a *Letter of Medical Necessity (LMN)*. See the Preauthorization Chapter of this guide for a sample Letter of Medical Necessity.

16. Q. When is the appropriate time to submit a Letter of Medical Necessity (LMN)?

Usually, the LMN is submitted during the pre-certification/preauthorization process, and is prepared by the clinician (provider of service). The letter of medical necessity is also used in the appeals process when a claim has been denied because the insurance company deemed TheraTogs to not be medically necessary. Clinicians should always use the basic charting concepts when recording patient encounters, keeping in mind the documentation will make the difference in an insurance company's decision to pay a claim.



SAMPLE WAIVER OF FINANCIAL LIABILITY

NON-MEDICARE

I, _____, acknowledge that the service(s) and/or item(s) listed below may not be covered by my insurance plan because of a medical necessity determination. My provider of service, _____, feels the services(s) and/or item(s) are medically necessary for my condition, and I agree to follow his/her medical care regimen, which includes acceptance of the service(s) or item(s) in question.

The medical necessity of the service(s) and/or item(s) has been fully explained to me, and I understand the extent of the clinical situation.

I agree to pay, in full, for the service(s) and/or item(s) listed below, directly to my provider of service _____. If I cannot pay this amount in full, I agree to make payment arrangements with the billing staff.

I have read, signed and dated this form prior to the service(s) and/or item(s) listed below being rendered or furnished to me.

Service(s)/Item(s):
1. _____
2. _____
3. _____
4. _____

Fees (each Service/Item):
1. \$ _____
2. \$ _____
3. \$ _____
4. \$ _____

Total Patient Responsibility: \$ _____

Check appropriate box:

- I will pay for the service(s) and/or item(s) in full.
- I will need to make payment arrangements with the provider's billing staff.

I acknowledge I have received the above service(s) and/or item(s), or the delivery of such item(s) has been scheduled.

Patient Signature

Date

To be retained in the client's medical record.



MEDICARE - SAMPLE ADVANCED BENEFICIARY NOTICE (ABN)

In the event that Medicare denies coverage for TheraTogs, each provider of service (physician and/or therapist) must have a signed ABN on file in order to bill the patient.

The following is a Sample Waiver Form for Medicare beneficiaries:

- Medicare Beneficiary Waiver of Liability -

Medicare will only pay for services it determines to be "reasonable and necessary" under Section 1862(a)(1) of the Medicare law. If Medicare determines that a particular service, although it would otherwise be covered, is not "reasonable and necessary" under Medicare program standards, Medicare will deny payment for that service.

I understand that, in my case, Medicare may deny payment for the TheraTogs orthotic devices.

Patient's Acknowledgement and Agreement to Pay:

I have been notified by my doctor that he/she believes that, in my case, Medicare is likely to deny payment for the services identified above. If Medicare denies the payment, I agree to be personally and fully responsible for payment.

Signed,

Patient Signature

Date

REFERENCES

Note: Listed below are published research studies specific to the use of TheraTogs. A complete list of references is available on the TheraTogs web site at: <http://theratogs.com/references.html>

Research Studies on TheraTogs

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Flanagan A, Krzak J, Johnson P, Peer M, Urban M. (2007) Evaluation of short-term intensive orthotic garment use in children with cerebral palsy. Gait Analysis Lab, Shriner's Hospital, Chicago, IL. Poster – CSM, APTA-Boston, MA.

Engelmeyer K, Meyer A, Quinslisk A, Wassell M, Ross S. (2007) The effect of TheraTogs™ on gait in a 5-year-old with hemiplegia. Poster – Combined Sections Meeting, APTA, Boston MA.

Rojas A., Weiss M., Elbaum L. The effect of TheraTogs on the gait of a child with cerebral palsy – a case study. Florida International Univ, Miami Florida.

Unpublished Studies Leading To Doctoral Dissertation:

Feldman C, Robinson CE. The Effects of TheraTogs™ on the Gait and Function of a Child with Spastic Diplegic Cerebral Palsy. Doctoral thesis. 2005. Pacific University.

GLOSSARY
GLOSSARY OF ACRONYMS

A

ABN Advance Beneficiary Notice
AMA American Medical Association

B

BCBSA Blue Cross and Blue Shield Association

C

CHAMPUS Civilian Health and Medical Program of the Uniformed Services
CMN Certificate of Medical Necessity
CMS Centers for Medicare and Medicaid Services
COB Coordination of Benefits
CPT Current Procedural Terminology

D

DF Dorsiflexion
DFA Dorsiflexion Assist
DHHS Department of Health and Human Services
DME Durable Medical Equipment
DMECS Durable Medical Equipment Coding System
DMEPOS Durable Medical Equipment, Prosthetics, Orthotics and Supplies
DMERC Durable Medical Equipment Regional Carrier
DOS Date of Service
Dx Diagnosis

E

EOB Explanation of Benefits

H

HCPCS Healthcare Common Procedure Coding System
HHA Home Health Agency
HMO Health Maintenance Organization

I

ICD-9-CM International Classification of Diseases, 9th Revision, Clinical Modification

L

LMN Letter of Medical Necessity

M

MCO Managed Care Organization
MFS Medicare Fee Schedule

N

NPI National Provider Identifier

P

PCP Primary Care Provider
PIN Provider Identification Number
POS Point of Service Program
PPO Preferred Provider Organization

S

SADMERC Statistical Analysis DME Regional Carrier
SI Sensory Integration
SPD Sensory Processing Disorder
SOF Signature on file
SOS Site-of-Service

T

TPA Third Party Administrator

U

UE Upper Extremity
UPIN Unique Physician Identification Number

GLOSSARY OF TERMS

A

Advance Beneficiary Notice: A form signed by Medicare beneficiaries, certifying that they have been notified that Medicare will (or is likely to) deny payment for a service or item provided and that the patient may have to pay the provider directly.

Appeal: A process where the provider and/or beneficiary exercises their right to request a review of a contractor determination to deny coverage or payment for a service in full or in part.

B

Beneficiary: A person eligible to receive benefits under an insurance plan.

C

Certificate of Medical Necessity: A form required by Medicare and some third-party payers to establish the medical necessity of certain DME. The form, completed by both the physician and the supplier, indicates the medical diagnosis and other information pertinent to the device.

CHAMPUS: The Civilian Health and Medical Program of the Uniformed Services, now known as TRICARE. A federally funded comprehensive health benefits program administered by the Department of Defense to provide health care benefits for military retirees as well as families of active duty, retired, and deceased service members.

CHAMPVA: The Civilian Health and Medical Program of the Department of Veteran Affairs. A federally funded health benefits program to provide health care benefits to families of a 1) veteran who is 100% permanently and totally disabled, 2) veteran who died from a VA-rated service connected disability, 3) veteran who at the time of death was 100% permanently and totally disabled, or 4) military member who died in the line of duty.

Claim: A demand to an insurer, by the insured person or provider acting on behalf of the insured, for payment of benefits under a policy.

CMS (Centers for Medicare and Medicaid Service): The U.S. government agency with responsibility for the administration of the Medicare and Medicaid programs.

CMS-1500: A universal insurance claim form mandated for Medicare billing and generally accepted by all insurance carriers for outpatient-based health care providers. Physicians and medical suppliers use the HCFA 1500 claim form.

Coding: A mechanism for identifying and defining medical services using a standardized listing of alphanumeric codes.

Co-insurance: A type of cost-sharing where the beneficiary of the health insurance plan is responsible for a specified percentage of health care service costs and/or is responsible for a specified amount per unit of service.

Co-payment: A cost-sharing arrangement in which a plan member pays a specified charge for a specified service, such as \$10 for an office visit. The member is usually responsible for payment at the time the health care is rendered. Typical co-payments are fixed or variable flat amounts for physician office visits, prescriptions, or hospital services.

Coverage: A term used to describe the potential payment status of a product or health service for which an insurer may provide payment.

Covered Expenses: Hospital, medical and other types of healthcare expenses incurred by the insured or beneficiary entitling him or her to a payment of benefits under a health insurance policy, (i.e., the type and amount of expense which will be considered in the calculation of benefits).

Covered Services: Covered services under the Medicare and other third-party payment programs are the services and supplies for which Medicare or other third parties will reimburse. Covered services under the Medicaid program consist of a combination of mandatory and optional services within each state. Covered services under the Medicare and Medicaid programs are defined and limited by federal statute. Covered services under private health benefit programs are defined and limited by contract.

CPT (Current Procedural Terminology): A coding system maintained by the American Medical Association to describe physician services and procedures.

Custom-fabricated: An orthotic made from basic materials on a case-by-case basis, by using actual measurements or molds of the patient.

Custom-fitted: A pre-manufactured orthotic that can be adjusted to fit the patient by bending, trimming, or with other minimal efforts.

D

Deductible: A stipulated amount which the insured is required to pay toward the cost of medical treatment before the benefits of the insurance policy or program take effect. Deductibles are usually per year of coverage (i.e., annual) and are required before any benefits are payable.

Denial: The refusal of an insurer to cover an item or service under a health care plan or program.

DMERC: One of four Medicare entities (Regions A, B, C, D) responsible for processing and paying Medicare claims for specific durable medical equipment, prosthetics, orthotic devices and supplies.

E

EOB (Explanation of Benefits): A form received from the insurer explaining the benefits that were paid and/or charges that were rejected.

Explanation of Medicare Benefits: A statement from Medicare that reports the specifics about a claim's adjudication or denial.

F

Fee Schedule: A list of predetermined payments for medical services. Medicare Part B reimburses physicians based on a fee schedule.

H

HCFA (Health Care Financing Administration): The U.S. Government agency with responsibility for the administration of the Medicare and Medicaid programs. On June 14, 2001, the agency name changed to the Centers for Medicare and Medicaid Services (CMS).

HCFA-1500: See CMS-1500.

HCPCS Level II Codes: Level II or national codes which supplement the CPT coding system and are used for supplies, medications, orthotic devices, prosthetics, items of durable medical equipment, special services, dental services, ambulance services, etc. HCPCS are recognized and used by Medicare and the majority of health care insurers.

I

ICD-9-CM (International Classification of Diseases, 9th Edition, Clinical Modification): A standardized system of describing diagnoses and procedures. The coding and terminology in the system provide a uniform language that is designed to accurately designate primary and secondary diagnosis and provide for reliable, consistent communication on claim forms.

M

Managed Care: A general term for organized networks of doctors and hospitals in order to give people access to quality, cost-contained health care. HMOs were the earliest form of managed care.

Medical Necessity: Medical information justifying that a service rendered was reasonable and appropriate for the diagnosis or treatment of a medical condition.

Medicare: A federal health insurance program for people over 65, those eligible for Social Security disability payments, and those with end-stage renal disease.

Medicare Advantage: Under the Balanced Budget Act of 1997 (BBA97), Congress created a new Medicare Part C, known as Medicare Advantage, which allows CMS to contract with a number of managed care organizations (MCOs) including, but not limited to, health maintenance organizations (HMOs), preferred provider organizations (PPOs) and provider service organizations (PSOs). Beneficiaries have the choice during an open enrollment period each year to enroll in a Medicare Advantage plan or to remain in traditional Medicare.

Medigap Insurance: Health insurance policies that provide benefits for services and costs not covered by Medicare, such as deductibles and co-insurance or items not covered under the Medicare program.

Modifier: Typically a two-position code used with HCPCS codes to indicate that the service has been changed or altered in some way.

N

National Supplier Clearinghouse: The entity that approves providers and medical equipment vendors as “suppliers” under the Medicare program, issuing an identification number to approved applicants.

National Supplier Identification Number: A provider or other healthcare professional uses this number to submit claims for DME they dispense. The number is obtained through an application submitted to the National Supplier Clearinghouse.

Non-Covered Service: The service: 1) does not meet the requirements of a Medicare benefit or insurance plan category, or 2) is statutorily excluded from Medicare coverage on grounds other than 1862(a)(1) or is not reasonable and necessary under 1862(a)(1).

O

Orthosis: A brace used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a diseased or injured part of the body.

Orthotics: See orthosis.

P

Part A: Medicare coverage that includes inpatient hospital, home health, nursing home, and other inpatient care.

Part B: Medicare coverage that provides payment for physician, outpatient services and most DME.

Point of Service Plan (POS): A type of managed care organization, which differs from others in that insureds who decide to go outside the plan for health care services receive reduced benefits.

Preauthorization (Prior Authorization): An assessment of health care services by the insurer in advance of provision of services by the provider. This may be required under the health care plan.

Preferred Provider Organization (PPO): An arrangement whereby an insurer or managing entity contracts with a group of health care providers who furnish services at lower than usual fees in return for prompt payment and a certain volume of clients.

Primary Care Provider (PCP): A healthcare professional who acts as a member's personal healthcare manager. The PCP evaluates a client's medical condition and either treats the condition or coordinates required healthcare services.

Principle Diagnosis: The diagnosis that is judged to be the principle reason for hospitalization or other medical care.

S

SADMERC: The Medicare entity that analyzes claims for DME to identify coding trends and irregularities. SADMERC also performs code verification reviews for providers and suppliers who do not know which code to report for specific items of DME. Manufacturers and/or vendors with new devices must submit a device description to SADMERC to receive an assigned HCPCS code for each device.

Soft goods: A term used for medical devices such as braces, splints, joint supports and protectors, cervical pillows and other orthopedic-oriented items.

Superbill: A document that lists commonly assigned diagnosis and procedure codes, used by health care providers during patient encounters. The superbill is no longer accepted by Medicare and most third-party payers as a substitute for the CMS-1500 claim form.

Support: An item that provides stabilization, but not immobilization, to an injured or disabled part of the body.

T

Third-party administrator: An insurance company or other entity that performs administrative tasks and functions for another entity or program, such as the Medicare program.

Third-Party Payer: An organization other than the patient or health care provider involved with the financing of health care services.

TRICARE: The Civilian Health and Medical Program of the Uniformed Services, formerly known as CHAMPUS. A federally funded comprehensive health benefits program administered by the Department of Defense to provide health care benefits for military retirees as well as families of active duty, retired, and deceased service members.