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Comments and Responses Regarding Draft Local Coverage Determination: Outpatient Physical and Occupational Therapy Services

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Outpatient Physical and Occupational Therapy Services LCD. The official notice period for the final LCD begins on May 15, 2008, and the final determination will become effective on July 1, 2008.

Unless otherwise specified, *italicized* text represents quotation from CMS sources.

Comment: Several commenters noted that this draft LCD, while titled Physical Medicine and Rehabilitation, was written more toward physical therapy and occupational therapy. In addition, other commenters requested that we clarify that the LCD applies to the "outpatient" therapy benefit.

Response: We changed the title to "Outpatient Physical and Occupational Therapy Services." In addition, we added the following clarification, "This Local Coverage Determination (LCD) describes the coverage limits of outpatient physical and occupational therapy services under Medicare Part B, billed to either the Medicare Fiscal Intermediary (FI) or Medicare Carrier when services are provided under a therapy plan of care."

Comment: Several commenters questioned the personnel authorized to provide outpatient therapy services; namely that therapists who are not licensed can provide therapy services incident to a physician, and that athletic trainers are not considered qualified providers of therapy services. In addition, many commenters noted that the LCD listing of authorized personnel differed from their state practice acts.

Response: The LCD describes Medicare coverage limits and requirements for outpatient therapy services. NGS has not expanded or contracted the authorized personnel requirements as set forth by the Centers for Medicare and Medicaid Services (CMS). According to CMS Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 230.5, "When therapy services are performed incident to a physician's/NPP's service, the qualified personnel who perform the service do not need to have a license to practice therapy, unless it is required by state law. The qualified personnel must meet all the other requirements except licensure." In addition, "the statute 1862(a)(20) requires that payment be made for a therapy service billed by a physician/NPP only if the service meets the standards and conditions--other than licensing--that would apply to a therapist."

CMS in Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 220(A), under the definition of THERAPY, has defined that therapy services are those skilled rehabilitative services provided according to the

standards and conditions in CMS manuals, within their scope of practice by qualified professional and qualified personnel, as defined in the manuals.

For clarification, the revised LCD will include the following definitions:

- **CLINICIAN** refers to a physician, nonphysician practitioner (physician assistant, clinical nurse specialist and nurse practitioner) or a therapist (but not to an assistant, aide or any other personnel providing a service within their scope of practice and consistent with state and local law. *Clinicians make clinical judgments and are responsible for all services they are permitted to supervise. Services that require the skills of a therapist may be appropriately furnished by clinicians, that is, by or under the supervision of qualified physicians/NPPs when their scope of practice, state and local laws allow it and their personal professional training is sufficient to provide to the beneficiary skills equivalent to a therapist for that service.*
- **QUALIFIED PROFESSIONAL** means a physical therapist, occupational therapist, physician, nonphysician practitioner (NPP) who is licensed or certified by the state to perform therapy services. *Qualified professionals may also include physical therapist assistants (PTA) and occupational therapy assistants (OTA) when working under the supervision of a qualified therapist, within the scope of practice allowed by state law.*
- **QUALIFIED PERSONNEL** means staff (auxiliary personnel) who have been educated and trained as therapists and qualify to furnish therapy services only under direct supervision incident to a physician or NPP. *Qualified personnel may or may not be licensed as therapists but meet all of the requirements for therapists with the exception of licensure.*

CMS, in Publication 100-02, *Medicare Benefit Policy Manual*, Chapter 15, Section 230.5, reiterates that only qualified professionals/personnel may provide and bill for therapy services. As noted, *“Regardless of any state licensing that allows other health professionals to provide therapy services, Medicare is authorized to pay only for services provided by those trained specifically in physical therapy, occupational therapy or speech-language pathology. That means that the services of athletic trainers, massage therapists, recreation therapists, kinesiotherapists, low vision specialists or any other profession may not be billed as therapy services.”*

Please keep in mind that if your state law is more restrictive than the Medicare guidelines, you must follow your state law. Because this LCD covers many states, NGS is not able to incorporate language consistent with each state. Providers should be aware of the regulations within their state.

Comment: Many commenters were concerned with the language in the LCD which provides number of services per day or number of treatments guidance related to various therapy interventions listed in the *Indications and Limitations of Coverage and/or Medical Necessity* section of the LCD. A number of commenters suggested that NGS was applying a “rule of thumb”, which is prohibited by CMS.

Response: The medical necessity of therapy services must be justified for Medicare payment to be made. The intent of providing the number of services per day or number of treatments is not to create a rule of thumb, but to provide guidance to providers of therapy services to ensure that the documentation in the medical record adequately justifies the medical necessity of services, including the skilled nature of the treatment, to allow payment. This guidance represents the experience of the NGS medical review department (physicians, therapist and nurse reviewers), standards established by other Medicare contractors, and other sources.

Please note, however, that edits for maximum billable units will be established as documented in the *Utilization Guidelines and Maximum Billable Units per Date of Service* section of the LCD.

Comment: Many commenters expressed concern regarding the non-coverage listing for “assessment for non-covered items (e.g., DME products)” because, while CMS may not pay for some DME or adaptive equipment, the skills of a therapist may be necessary to evaluate and train the patient in the use of the equipment.

Response: This item has been removed from the list of non-covered Miscellaneous Services. In addition, the bullet under the initial evaluation section which stated “An evaluation by a therapist is not covered when the evaluation is for a non-covered service” has also been removed. However, in all cases, the medical necessity of completing a skilled therapy evaluation must be established in the documentation for payment to be made.

Comment: Many commenters suggested that we reconsider the statement, “Therapy is not required to effect improvement or restoration of function where a patient suffers a transient and easily reversible loss or reduction in function which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities.”

Response: This quote is from CMS Publication 100-02, *Medicare Benefit Policy Manual*, chapter 15, section 220.2(C)). NGS will maintain this coverage guideline in the LCD to assure that providers are aware that not all patients who exhibit a reduction in function require skilled therapy to restore lost function.

Comment: Regarding the LCD statement, “If function is not likely to improve because of a patient’s limited ability to comprehend instructions, follow directions, or remember skills required to achieve an increase in function, rehabilitative therapy is not covered”, several commenters voiced a concern in line with this comment submitted by the AOTA: “While AOTA agrees that a large number of the restorative rehabilitation goals in occupational therapy require the patient’s ability to follow directions and remember skills, there are at times rehabilitation goals that will not require these cognitive skills. Examples include sitting and standing balance activities that help a patient recover the ability to sit upright in a seat or wheelchair or safely transfer from the wheelchair to a toilet. Second, there are patients, such as patients with head injury or traumatic brain injury who upon initial evaluation do not have the ability to follow directions or remember skills. Yet, that may be one of their treatment goals, to recover those abilities. AOTA is concerned that the proposed language may mislead local contractors to automatically deny coverage for all patients who have severe cognitive impairments upon admission.”

Response: The LCD language has been revised to read,

If function is not likely to improve because of a patient’s limited ability to comprehend instructions, follow directions, or remember skills that are necessary to achieve an increase in function, rehabilitative therapy is not covered. However, limited services in these circumstances may be covered with supportive documentation, if the skills of a therapist are required to establish and teach a caregiver a safety or maintenance program.

- This does not apply to the limited situations where rehabilitative therapy is reasonable and achieving meaningful goals is appropriate, even when a patient does not have the ability to comprehend instructions, follow directions or remember skills. Examples include sitting and standing balance activities that help a patient recover the ability to sit upright in a seat or wheel chair, or safely transfer from the wheelchair to a toilet.

- This also does not apply to those patients who have the potential to recover abilities to remember or follow directions, and treatment may be aimed at rehabilitating these abilities, such as following a traumatic brain injury.

Comment: Many commenters disagreed with the statement, “The skills of a therapist are not required to carry out the maintenance program.”

Response: The above statement is taken from CMS Publication 100-02, *Medicare Benefit Policy Manual*, chapter 15, section 220.2(D). However, we added the following additional clarifying language,

“The specialized skill, knowledge and judgment of a therapist may be required, and services are covered, to design or establish the maintenance program, assure patient safety, train the patient, family members, caregiver, and/or unskilled personnel and make infrequent but periodic reevaluations of the program. The services of a qualified professional are not necessary to carry out a maintenance program, and are not covered under ordinary circumstances. The patient may perform such a program independently or with the assistance of unskilled personnel, caregivers or family members. For circumstances in which the patient’s safety is at risk, services may be covered when the skilled maintenance program is carried out by the qualified professional/personnel (e.g., where there is an unhealed, unstable fracture) with documented justification.”

Comment: A number of commenters were concerned that the LCD appeared to not cover “rehabilitative” therapy for beneficiaries with chronic, progressive conditions, but would only cover limited maintenance therapy for these beneficiaries.

Response: The following paragraph was added to the section on maintenance therapy to clarify that some patients with chronic progressive conditions may benefit from rehabilitative therapy.

“When patients with chronic progressive conditions experience a recent deterioration of function, rehabilitative therapy may be appropriate and reasonable to assist the patient in restoring lost function. Other times, the intent of therapy is not necessarily rehabilitative, but to develop a maintenance program to delay or minimize functional deterioration. Instruction in a maintenance program required to delay or minimize functional deterioration in patients suffering from a chronic disease requires supporting documentation when more than 2-4 visits are provided. In addition, therapy may be intermittently necessary to determine the need for assistive equipment and/or establish/revise a program to maximize function.”

Comment: Several commenters questioned why CPT code 97532 (cognitive skill training) included ICD-9 codes while the other CPT codes do not. Commenters also suggested that if ICD-9 codes are used, that the list be expanded, for example, to include cognitive changes that occur with traumatic brain injury such as TBI or CVA, or symbolic dysfunction that occurs in conjunction with organic brain damage.

Response: It has been the experience of NGS that this code is frequently used incorrectly. This code has been used for computer related procedures to prevent further decline in patients with declining memory, which would be a noncovered intervention. Therefore, to assure that the service is provided to appropriate patients, NGS has included a list of covered diagnoses. We do believe that the current language of the LCD does provide coverage for medically necessary cognitive skills training for such patients as those experiencing

cognitive changes due to TBI or CVA. The ICD-9 codes listed in the LCD should appropriately capture these patients when also billed with the ICD-9 code for the underlying disorder (cause), as directed in the LCD.

Consideration must always be given to the coverage guideline that requires complexity in both the patient and the treatment provided for Medicare payment to occur. While we understand that some Medicare beneficiaries may experience a level of cognitive or memory loss, for coverage to occur the patient must require the unique skills of a therapist to improve their functioning. If the patient's condition could improve through a community based program or a computer related procedure that does not require the immediate, 1:1 intervention of the qualified professional/personnel, the services would not be covered.

Comment: One commenter asked that NGS provide an allowed reevaluation frequency.

Response: Medicare guidelines for reevaluations do not allow for any type of routine performance of reevaluations. Reevaluations will only be covered when the guidelines are met as noted in the LCD.

Comment: Several commenters objected to the phrase "Additional Documentation Requirements" as this phrase seemed to contradict the CMS minimal documentation requirements.

Response: As suggested by one commenter, NGS changed the phrase to "Supportive Documentation Recommendations." NGS is aware of the minimal documentation requirements established by CMS. The Supportive Documentation Recommendations are provided as helpful suggestions to assist providers in documenting to support the medical necessity and skilled nature of the services provided.

Comment: Several commenters objected to the non-coverage of driving assessments, noting that driving was required by many Medicare beneficiaries as part of community reintegration.

Response: For Medicare purposes, when services provided are related solely to driving, they are not reasonable or necessary for the diagnosis or treatment of an illness or injury and are excluded from coverage under the program by SSA 1862(a)(1).

Comment: The APTA and other commenters requested that Nerve Conduction Studies (NCS)/Electromyography (EMG) coverage guidance be added to this LCD.

Response: NGS will refer any therapy coverage guidance regarding this topic to the upcoming NGS LCD for Nerve Conduction Studies (NCS)/Electromyography (EMG).

Comment: Several commenters recommended that NGS include phonophoresis, not as a separate service from ultrasound, but as an ultrasound and reimburse for this service under CPT code 97035.

Response: The LCD has been revised to read,

"Phonophoresis (the use of ultrasound to enhance the delivery of topically applied drugs) will be reimbursed as ultrasound, billable using CPT 97035. Separate payment will not be made for the contact medium or drugs."

Comment: Several commenters disagreed with the non-coverage decision of ultrasound for wounds.

Response: NGS will continue to list ultrasound as a noncovered treatment for wounds. The efficacy of deep thermal or low frequency ultrasound has not been sufficiently proven for wound care. Coverage will not be made for ultrasound for wounds billed under any code, including CPT 97035, Category III CPT code 0183T, or an unlisted code.

Comment: Several commenters disagreed with the non-coverage of therapy interventions for pelvic floor dysfunctions (not including incontinence).

Response: While NGS understands that pain and discomfort associated with pelvic floor dysfunctions can cause functional limitations, there is insufficient evidence that therapy interventions are the most effective, efficient treatment for these conditions.

Comment: Several commenters did not agree with the inclusion of vestibular ocular reflex training in the list of non-covered services.

Response: The evidence submitted did not support the efficacy for vestibular ocular reflex training and as such will remain noncovered.

Comment: Many commenters did not agree with the inclusion of iontophoresis in the list of non-covered services.

Response: The evidence submitted did not support the efficacy for iontophoresis and as such will remain noncovered.

Comment: Several commenters requested that NGS provide a definition of “screening” in the LCD.

Response: A description of screening has been added to the LCD.

Comment: Many commenters did not agree with the language in the LCD that restricted the use of a community center pool. The language in the LCD was as follows,

For example, a therapist in private practice may furnish aquatic therapy in a community center pool. As required in other settings (such as rehabilitation agencies and CORFs), the practice would have to rent or lease the pool for those hours, and the use of the pool during that time would have to be restricted to the therapist’s patients, in order to recognize the pool as part of the therapist’s own practice office during those hours.

Response: The pool language above is a direct quote from CMS publication 100-02, *Medicare Benefit Policy Manual*, chapter 15, section 230.4. Because CMS is in the process of revising this language, NGS has removed this paragraph from the LCD. However, as long as this paragraph remains in the CMS manuals, the restrictions still apply.

Comment: A number of providers questioned the LCD limitations of coverage related to paraffin bath (CPT 97018).

Response: Paraffin bath treatments, like hotpacks and whirlpools, rarely require the unique skills of a therapist to apply. The fact that a patient may benefit from the use of paraffin bath does not necessarily make it skilled, except for circumstances as outlined in the LCD.

Comment: The AOTA requested that dysphagia codes be added to this LCD.

Response: NGS will refer any therapy coverage guidance regarding this topic to the upcoming NGS LCD on dysphagia that will be published in the near future.

Comment: Several commenters suggested that CPT code 64550 (application of surface neurostimulator) is not an operative/postoperative code and that it may be used for the initial instruction and issuing of a TENS unit for home use.

Response: CPT 64550 is in the surgery section of the CPT manual. The LCD advises that when one-to-one patient teaching is provided, to ensure safe, effective use of a home TENS unit, the timed code 97032 better reflects the 1:1 nature when providing this skilled service.