From Regulations to Records: Charting for Compliance

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Overview

- Despite the Public Health Emergency's stresses on home health agency operations, CMS' medical review (MR) activities have fully resumed; presenting an additional challenge to home health agency operations if a MR review is triggered.
- There are multiple Medicare, Medicare Advantage, and commercial insurance reviewers that are checking medical records for accurate claim payment. These encompass newly billed and reopened old claims when a review edit is triggered. Most home health agencies focus on survey compliance and do not evaluate their medical records from a compliance and payment perspective. This can cause great difficulties if caught up in one of these Medical Reviews, Audits, or Probes.
- Key to a successful outcome from a MAC Targeted Probe or Educate (TPE) review, Unified Program Integrity Reviewer (UPIC) audit; Recovery Audit Contractor (RAC), Supplemental Medical Review Contractor (SMRC), or Comprehensive Error Rate Testing (CERT) review is having compliant clinical record content. The content should reflect the required rules and regulations and should be included when the record is generated—not after.
- This presentation starts with key coverage requirements from Medicare rules and regulations—and what they actually contain. It then covers how these should be reflected in the home health record to address known denial reasons. This includes both nursing and therapy medical necessity requirements for coverage. By linking requirements to known denial reasons it shows how documentation can avoid a negative outcome.
- This also provides the basis for staff education so the benefit of prevention can be achieved. Current staff can learn how to "chart it right": new staff learn from the actual regulations to "start it right." The items covered also apply to Medicare Advantage medical reviews.

Objectives

Presentation attendees will take back to their agency:

- Knowledge of key Medicare Benefit Policy Manual requirements
- Ability to state the most common denial reasons issued by Medicare and Medicare Advantage reviewers
- Actions to train staff and implement the actual regulatory requirements into charts to improve RCD documentation flow and medical review outcomes

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Top NGS Denial Reasons

- 55H1F – No certification present in documentation submitted
- 55H1S – Face-to-face encounter requirements not met
- 55H1V – Subsequent certification not signed by physician
- 55H20 – Claim denied after review
- 55H3A – Skilled observation not needed from start of care
- 55HTB – Medicare requires a plan of care be established
- 55P00 – Services denied or changed based on review of ZPIC
  - Source: www.ngsmedicare.com, Top Claim Errors [accessed 3/11/22]

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Common Denial Reasons

- Nursing provided while a patient has no change in condition, medications or treatment
- Nursing instruction is repetitive and redundant
- Nursing instruction in generic
- Therapy reassessment requirements not met (comparison to prior)
- Therapy interventions repetitive and for prolonged period of service

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CMS Coverage Requirements

- Homebound
- Nursing skill/necessity
  - Observation/assessment
  - Teaching/instruction
  - Medical management
  - Medication administration
  - Wound care
  - Catheter care
  - Psychiatric nursing
- Therapy skill/necessity
  - Assessment/reassessment
  - Goals
  - Interventions
- Certification
  - Present, timely, complete
- Face-to-face encounter
  - Timely
  - Allowed practitioner
  - Related to primary reason for HH
  - Supports need, services, homebound
  - Relationship of acute/post-acute to community physician
- Plan of Care
  - Present, timely, complete
- Dependent services

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MBPM Pub. 100-02, Chapter 7 Key Regulations

- 30.1 Confined to Home
- 30.2 Services under a Plan of Care
- 30.3 Under the Care of a Physician
- 30.5.1 Physician Certification
  - 30.5.1.1 Face-to-Face Encounter
  - 30.5.1.2 Supporting Documentation
- 30.5.2 Physician Recertification

- 40.1.1 Skilled Nursing Service
  - 40.1.2.1 Observation/Assessment
  - 40.1.2.2 Management & Evaluation
  - 40.1.2.3 Teaching/Instruction
  - 40.1.2.4 Medication Administration
  - 40.1.2.7 Catheters
  - 40.1.2.8 Wound Care
  - 40.1.2.13 Venipuncture
  - 40.1.2.15 Psychiatric
- 40.2.1 Skilled Therapy Services
- 50.2 Home Health Aide Services
- 50.3 Medical Social Services

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Code of Federal Regulations (CFR)

- 42 CFR 409.33: Examples of skilled services and the need for skilled services
- 42 CFR 409.41: Requirement for payment
- 42 CFR 409.42: Beneficiary qualifications for coverage of services
- 42 CFR 409.43: Plan of care requirements
- 42 CFR 409.44: Skilled services requirements
- 42 CFR 409.45: Dependent services requirements
- 42 CFR 409.48: Visits
- 42 CFR 424.22: Requirements for home health services
- 42 CFR 484.55: CoP, Comprehensive Assessment
- 42 CFR 484.60: CoP, Care planning coordination of services, and quality of care

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Other References

- 42 CFR 484.75: Skilled Professional Services
- CMS OASIS Guidance Manual
  - https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-D-Guidance-Manual-final.pdf
- ICD-10 Official Guidelines for Coding and Reporting
  - https://www.cms.gov/files/document/2021-coding-guidelines-updated-12162020.pdf

  - Websites accessed 3/25/22

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Medicare Advantage (MA)

- Most MA contractors CMS Traditional Medicare coverage requirements
  - Medicare Benefit Policy Manual (MBPM) IOM Pub. 100-02
  - Medicare Program Integrity Manual (PIM) IOM Pub. 100-08
  - Home Health Conditions of Participation 42 CFR 484
  - Medicare OASIS Guidance Manual
- Most MA contractors have significantly different appeals processes
  - Does not follow CMS Medicare Claims Processing Manual (MCPM) Pub. 100-04
  - Does not follow CMS appeals process of 42 CFR 405
- Most DO require face-to-face requirements, plan of care, certification, and coverage requirements (including therapy assessment/reassessment)

EMR and Compliance

- Electronic Medical Record (EMR) systems are used by home health agencies
- All provide some form of template for completion of OASIS, assessments, visits, summaries, communications, orders, etc.
- NO EMR system by itself will generate a compliant (fully billable) claim
- ALL EMR systems need correct CONTENT added to their template to generate a compliant (fully payable) claim

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Issues with EMR Systems

- Common deficiencies from Medical Review of EMR generated records
  - Difficult to read: type size, formatting, paragraph breaks, pagination, location of information
  - Clutter: too much content in Plan of Care and too many goals
  - Clutter: too much content in visit note to expect it was all covered within the time of the visit
  - Check-boxes: check-boxes ALONE will NEVER generate a compliant note
  - Check box options: generic content not clearly relatable to the patient status
  - Summaries (especially 60-day) have generic phrasing selected and check boxes
  - Missing required elements (e.g., therapy comparison of reassessment findings to prior assessment, therapy prior level of function)
  - Populates identical narrative content in multiple places in the record: does not add to compliance
  - Provides generic phrase options: “teach disease process”, “Condition unstable”, etc.

Compliant Charting

- Know what CMS coverage requirements expect
- Implement these in charting:
  - Avoid generic statements
  - Avoid check-box only charting
  - Use Narrative options to specifically address CMS requirements
  - Provide longitudinal—not “click & clutter” charting
- Recognize when care is unskilled (custodial):
  - Repetitive
  - Generic
  - Unrealistic
- Recognize when care is no longer appropriate or needed

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42 CFR 409.42 Beneficiary Qualifications for Coverage of Services

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements:

(a) *Confined to the home…*

(b) *Under the care of a physician...*

(c) *In need of skilled services.* The beneficiary must need at least one of the following skilled services as certified by a physician in accordance with the physician certification and recertification requirements for home health services under § 424.22 of this chapter.

(1) Intermittent skilled nursing services that meet the criteria for skilled services and the need for skilled services…These criteria are subject to the following limitations in the home health setting:

(i) In the home health setting, management and evaluation of a patient care plan is considered a reasonable and necessary skilled service when underlying conditions or complications are such that only a registered nurse can ensure that essential non-skilled care is achieving its purpose. To be considered a skilled service, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of licensed nurses to promote the patient's recovery and medical safety in view of the overall condition…

However, a service is not considered a skilled nursing service merely because it is performed by or under the supervision of a licensed nurse. Where a service can be safely and effectively performed (or self administered) by non-licensed staff without the direct supervision of a nurse, the service cannot be regarded as a skilled service even if a nurse actually provides the service.

(ii) In the home health setting, skilled education services are no longer needed if it becomes apparent, after a reasonable period of time, that the patient, family, or caregiver could not or would not be trained. Further teaching and training would cease to be reasonable and necessary in this case, and would cease to be considered a skilled service. Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.

42 CFR 409.42 (continued)

§ 409.42 Beneficiary qualifications for coverage of services.

To qualify for Medicare coverage of home health services, a beneficiary must meet each of the following requirements…

(c) (1) Intermittent skilled nursing that meet the criteria for skilled services and the need for skilled services found in § 409.32

(c) (2) Physical therapy services that meet the requirements of § 409.44(c).

(c) (3) Speech-language pathology services that meet the requirements of § 409.44(c).

(c) (4) Occupational therapy services in the current and subsequent certification periods (subsequent adjacent episodes)…initially qualify for home health coverage as a dependent service…if the beneficiary's eligibility for home health services has been established…Subsequent to an initial covered occupational therapy service, continuing occupational therapy services which meet the requirements of § 409.44(c) are considered to be qualifying services.

(*d)Under a plan of care*. The beneficiary must be under a plan of care that meets the requirements for plans of care specified in § 409.43.

(e)*By whom the services must be furnished.* The home health services must be furnished by, or under arrangements made by, a participating HHA.

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IOM Pub. 100-02, Ch 7; Section 30

Medicare Benefit Policy Manual (MBPM)

30 - Conditions Patient Must Meet to Qualify for Coverage of Home Health Services

To qualify for the Medicare home health benefit, under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, a Medicare beneficiary must meet the following requirements:

- Be confined to the home;
- Under the care of a physician;
- Receiving services under a plan of care established and periodically reviewed by a physician;
- Be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or
- Have a continuing need for occupational therapy.

For purposes of benefit eligibility…"intermittent" means skilled nursing care that is either provided or needed on fewer than 7 days each week or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

A patient must meet each of the criteria specified in this section. Patients who meet each of these criteria are eligible to have payment made on their behalf for services discussed in §§40 and 50.

42 CFR 409.44

Skilled services requirements

- 409.44(a) General
- 409.44(b) Skilled nursing care
- 409.44(c) Physical therapy, speech-language pathology services, and occupational therapy

These correspond to IOM Pub. 100-02, Chapter 7, Section 40

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Medicare Benefit Policy Manual (MBPM)

- The “regulations” for coverage
- Issued from CMS
- Internet-Only Manual (IOM)
- Publication 100-02
- Chapter 7 (Home Health)
- Presentation content from manual current thru ***Rev. 10738, 05-07-21***

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MBPM, IOM Pub. 100-02, Chapter 7

- Section 20 – Conditions to be Met for Coverage of Home Health Services
- Section 30 – Conditions Patient Must Meet to Qualify for Coverage of Home Health Services
- Section 40 – Covered Services Under a Qualifying Plan of Care

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Key Regulations for Coverage

- MBPM, Chapter 7 Sections
- 30.1.1 Homebound
- 40.1.1 Nursing Services
- 40.1.2.1 Nursing Observation & Assessment
- 40.1.2.2 Management & Evaluation
- 40.1.2.3 Teaching & Training

- MPBM Chapter 7, Sections
- 40.1.2.4 Medication Administration
- 40.1.2.7 Catheters
- 40.1.2.8 Wound Care
- 40.1.2.13 Venipuncture
- 40.1.2.15 Psychiatric Nursing
- 40.2.1 Therapy Services

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30.1.1 Patient Confined to the Home

An individual shall be considered “confined to the home” (homebound) if the following two criteria are met:

- 1. *Criterion One:*
  The patient must either:
  - Because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence

  OR
  - Have a condition such that leaving his or her home is medically contraindicated.

If the patient meets [at least] one of the *Criterion One conditions, then the patient must ALSO meet two additional requirements defined in Criterion Two.*

- 2. *Criterion Two:*
  - There must exist a normal inability to leave home;

  AND
  - Leaving home must require a considerable and taxing effort.

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30.1.1 Homebound Longitudinal Charting

- Homebound shown by either:
  - BOTH Criterion One requirements (assistive device, special transportation, assistance of another person—or— medically contraindicated) met, then ALSO have BOTH Criterion Two requirements (normal inability to leave home, requires a considerable and taxing effort) met = homebound
  - If only ONE Criterion One requirement met, then ALSO have BOTH Criterion Two requirements met to support homebound
  - If neither Criterion One requirement met = not homebound
- **Standardized phrases reflecting the patient's condition (e.g., repeating the words "taxing effort to leave the home") in the patient's chart by themselves do not demonstrate that Criterion Two has been met**.
- **Longitudinal clinical information about the patient's health status is typically needed to sufficiently demonstrate a normal inability to leave the home and that leaving home requires a considerable and taxing effort**. (Such as diagnosis, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results)

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30.1.1 Allowable Reasons to Leave Home

To be homebound the absences from the home must be:

- **Infrequent, or**
- **for periods of relatively short duration, or**
- **are attributable to the need to receive health care treatment**.

Adult day care must be licensed, certified, or accredited.

Attending a religious service is deemed to be an absence of infrequent or short duration.

Occasional absences from the home for nonmedical purposes (occasional trip to the barber, a walk around the block or a drive, attendance at a family reunion, funeral, graduation, or other infrequent or unique event) can occur if such absences are **infrequent, of relatively short duration, and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.**

Psychiatric Condition:

A patient with a psychiatric illness that is manifested in part by a refusal to leave home or is such a nature that it would not be considered safe for the patient to leave home unattended even if they have no physical limitations.

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30.1.1 Homebound: Ability Vs. Choice

- The aged person who does not often travel from home solely because of **feebleness and insecurity brought on by advanced age would not be considered confined to the home.**
- **If some services cannot be provided at the patient's residence because equipment is required that cannot be made available there, the home health agency may make arrangements with a hospital, SNF, or a rehabilitation center to provide these services on an outpatient basis.** However, even in these situations the patient must be considered confined to home and meet both criteria listed above.
- If a question is raised as to whether a patient is confined to the home, the home health agency will be requested to furnish the Medicare contractor with the information necessary to establish that the patient is homebound as defined above.

Homebound: Key Considerations

- Assistive device needed
- Physical limitations
- Psychiatric issues
- Frequency of leaving home
- Need for assistance (person, transportation)
- Safety issues
- Document where to/when/how often leaving
- Homebound is not simply a choice

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40.1.1 Nursing Medical Necessity

- Section 40.1 gives general requirements for nursing service:
  A service that requires the skills of a nurse to be provided safely and effectively continues to be a skilled service even if it is taught to the patient, the patient's family, or other caregivers.

  Skilled nursing service must be reasonable and necessary to the diagnosis and treatment of the patient's illness or injury within the context of the patient's unique medical condition.

A patient's overall medical condition, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time, should be considered in deciding whether skilled services are needed. A patient's diagnosis should never be the sole factor in deciding that a service the patient needs is either skilled or not skilled. Skilled care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable.

Home health regulations and home health Conditions of Participation (CoPs) require that the clinical record of the patient must contain progress and clinical notes**…**

It is expected that the home health records for every visit will reflect the need for the skilled medical care provided. These clinical notes are also expected to provide important communication among all members of the home care team regarding the development, course and outcomes of the skilled observations, assessments, treatment and training performed. Taken as a whole, the clinical notes are expected to tell the story of the patient's achievement towards his/her goals as outlined in the Plan of Care. In this way, the notes will serve to demonstrate why a skilled service is needed.

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40.1.1 Nursing Longitudinal Charting

Home health clinical notes must document, as appropriate:

- The history and physical exam pertinent to the day's visit, (including the response or changes in behavior to previously administered skilled services) and the skilled services applied on the current visit, and
- The patient/caregiver's response to the skilled services provided, and
- The plan for the next visit based on the rationale of prior results,
- A detailed rationale that explains the need for the skilled service in light of the patient's overall medical condition and experiences,
- The complexity of the service to be performed, and
- Any other pertinent characteristics of the beneficiary or home

Clinical notes should be written so that they adequately describe the reaction of a patient to his/her skilled care.

Clinical notes should also provide a clear picture of the treatment, as well as "next steps" to be taken. **Vague or subjective descriptions of the patient's care should not be used**. For example, terminology such as the following ***would not adequately describe*** the need for skilled care:

- Patient tolerated treatment well
- Caregiver instructed in medication management
- Continue with POC

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40.1.1 Outcomes & Skilled Need

Objective measurements of treatment outcomes should be provided and/or a clear description of the changed behaviors due to education programs should be recorded so that all concerned can follow the results of the applied services.

To be covered as skilled nursing services, the services must require the skills of a registered nurse, or a licensed practical (vocational) nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury as discussed in §40.1.1…and must be intermittent as discussed in §40.1.3. **Coverage of skilled nursing care does not turn on the presence or absence of a patient's potential for improvement from the nursing care, but rather on the patient's need for skilled care.**

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Skilled Nursing: Key Considerations

- Consistent with the nature and severity of the illness or injury, the patient's particular medical needs, and accepted standards of medical and nursing practice
- The home health records for every visit reflect the need for the skilled medical care provided
- Clinical notes document past status, current findings, and future plans to address these issues
- A need for the skills of a nurse must be shown
- If a non-medical person can safely perform it is not coverable
- Care must meet intermittent requirements
- Detail of actions taken is the key for coverage
- Outcomes of actions and teaching are needed to support coverage

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40.1.2.1 Observation and Assessment

- Observation and assessment of the patient's condition by a nurse are reasonable and necessary skilled services ***where*** **there is a reasonable potential for change in a patient's condition that requires skilled nursing** personnel to identify and evaluate the patient's need for possible modification of treatment or initiation of additional medical procedures **until the patient's clinical condition and/or treatment regimen has stabilized**.
- **Where a patient was admitted to home health care for skilled observation** because there was a reasonable potential of a complication or further acute episode, **but did not develop a further acute episode or complication, the skilled observation services are still covered for 3 weeks or so long as there remains a reasonable potential for such a complication or further acute episode.**
- Information from the patient's home health record must document the rationale that demonstrates that there is a **reasonable potential for a future complication or acute episode and, therefore, may justify the need for continued skilled observation and assessment beyond the 3-week period.**

40.1.2.1 Charting Observation and Assessment

- Such signs and symptoms as:
  - abnormal/fluctuating vital signs,
  - weight changes, edema,
  - symptoms of drug toxicity,
  - abnormal/fluctuating lab values,
  - respiratory changes on auscultation may justify skilled observation and assessment.
- Where these signs and symptoms are such that there is a reasonable potential that skilled observation and assessment by a licensed nurse will result in changes to the treatment of the patient, then the services would be covered.
- However, observation and assessment by a nurse is **not reasonable and necessary for the treatment of the illness or injury where fluctuating signs and symptoms are part of a longstanding pattern of the patient's condition which has not previously required a change in the prescribed treatment.**

Nursing Observation and Assessment: Key Considerations

- Valid for up to 3 weeks
  - From start of care
  - May apply to changes in condition, medication, treatment
- Not automatically covered for this initial period: must show need for service
- Then must demonstrate potential for continued change or instability AND need for nursing to evaluate these changes
- Changes in condition support continued coverage
- Lack of change in condition = custodial
- Changes in condition without change in plan of care = non covered (if found to be a long-standing pattern)

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40.1.2.2 Management & Evaluation of a Patient Care Plan

- Skilled nursing visits for management and evaluation of the patient's care plan are also reasonable and necessary where underlying conditions or complications require that **only a registered nurse can ensure that essential unskilled care is achieving its purpose.**
- For skilled nursing care to be reasonable and necessary for management and evaluation of the patient's plan of care, the complexity of the necessary unskilled services that are a necessary part of the medical treatment must require the involvement of skilled nursing personnel to promote the patient's recovery and medical safety in view of the patient's overall condition.

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Nursing Management & Evaluation: Key Considerations

- Evaluation of the care plan—not the patient
- Nursing is needed to manage unskilled care to prevent decline in patient condition
- Nursing service itself is not the skill—it is the supervision and interaction with unskilled caregivers
- A physician narrative statement is required on recertification Plan of Care for Management and Evaluation patients
- Registered Nurse only: not LPN/LVN

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Section 40.1.2.3 Teaching and Training Activities

- Teaching and training activities that require skilled nursing personnel to teach a patient, the patient's family, or caregivers how to manage the treatment regimen would constitute skilled nursing services.
- The test of whether a nursing service is skilled relates to the skill required to teach and not to the nature of what is being taught.
- Skilled nursing visits for teaching and training activities are reasonable and necessary where the teaching or training is **appropriate to the patient's functional loss, illness, or injury**.
- Where it becomes apparent after a reasonable period of time that the patient, family, or caregiver will not or is not able to be trained, then further teaching and training would cease to be reasonable and necessary. **The reason why the training was unsuccessful should be documented in the record.**
- **Notwithstanding that the teaching or training was unsuccessful, the services for teaching and training would be considered to be reasonable and necessary prior to the point that it became apparent that the teaching or training was unsuccessful, as long as such services were appropriate to the patient's illness, functional loss, or injury.**

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Section 40.1.2.3 Allowable Teaching Visits

- In **determining the reasonable and necessary number of teaching and training visits**, consideration is given to whether the teaching and training provided constitutes r**einforcement** of teaching provided previously in an institutional setting or in the home **or whether it represents initial instruction**.
- **Where the teaching represents initial instruction,** the complexity of the activity to be taught and the unique abilities of the patient are to be considered.
- **Where the teaching constitutes reinforcement,** an analysis of the patient's retained knowledge and anticipated learning progress is necessary to determine the appropriate number of visits. Skills taught in a controlled institutional setting often need to be reinforced when the patient returns home. Where the patient needs reinforcement of the institutional teaching, additional teaching visits in the home are covered.
- **Re-teaching or retraining** for an appropriate period may be considered reasonable and necessary where there is a change in the procedure or the patient's condition that requires re-teaching, or where the patient, family, or caregiver is not properly carrying out the task. **The medical record should document the reason that the re-teaching or retraining is required and the patient/caregiver response to the education**.

Section 40.1.2.3

NOT EXAMPLES OF SKILLED TEACHING

- “Teach on disease process…”
- “Instruct on home safety…”
- “Teach on emergency plan…”
- “Instruct on medications…”

What is needed to support skill:

- Which disease process?
- Why teaching on safety after first visit?
- Why teaching on emergency plan more than once?
- Which medication?
- Changed medication?
- Exacerbation of disease present?

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Nursing Teaching and Training: Key Considerations

- There is no specific limit to length of teaching/training
- Often supports coverage after observation/assessment is no longer valid
- On new/changed treatments, medications, or diagnoses
- Limitations on recipient's learning ability must be identified
- Content of training must support that skills of a medical professional needed
- Not all medications/diagnoses need instruction
- Response and progress of teaching must be recorded
- Limited coverage for reinforcement and re-training

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Section 40.1.2.4 Administration of Medications

Although drugs and biologicals are specifically excluded from coverage…the services of a nurse that are required to **administer** the medications safely and effectively may be covered if they are reasonable and necessary to the treatment of the illness or injury.

Injections
Intravenous, intramuscular, or subcutaneous injections and infusions, and hypodermoclysis or intravenous feedings require the skills of a licensed nurse to be performed (or taught) safely and effectively.
There must be a medical reason that the medication cannot be taken orally.
The frequency and duration of the administration of the medication must be within accepted standards of medical practice or there must be a valid explanation regarding the extenuating circumstances to justify the need for the additional injections.

Vitamin B-12 injections are considered therapy only for the following conditions:

- Specified anemias: pernicious anemia, megaloblastic anemias, macrocytic anemias, fish tapeworm anemia;
- Specified gastrointestinal disorders: gastrectomy, malabsorption syndromes such as sprue and idiopathic steatorrhea, surgical and mechanical disorders such as resection of the small intestine, strictures, anastomosis and blind loop syndrome;
- Certain neuropathies: posterolateral sclerosis, other neuropathies associated with pernicious anemia, during the acute phase or acute exacerbation of a neuropathy due to malnutrition and alcoholism.

For a **patient with pernicious anemia caused by a B-12 deficiency,** intramuscular or subcutaneous injection of vitamin B-12 at a dose of from 100 to 1000 micrograms no more frequently than once monthly is the accepted reasonable and necessary dosage schedule for maintenance treatment. More frequent injections would be appropriate in the initial or acute phase of the disease until it has been determined through laboratory tests that the patient can be sustained on a maintenance dose.

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40.1.2.4 Insulin Administration

Insulin Injections

Insulin is customarily self-injected by patients or is injected by their families. ***However, where a patient is either physically or mentally unable to self-inject insulin and there is no other person who is able and willing to inject the patient, the injections would be considered a reasonable and necessary skilled nursing service.***

The prefilling of syringes with insulin (or other medication that is self injected) does not require the skills of a licensed nurse and, therefore, is not considered to be a skilled nursing service. If the patient needs someone only to prefill syringes (and therefore needs no skilled nursing care on an intermittent basis, physical therapy, or speech language pathology services) than he/she does not qualify for any Medicare coverage of home health care. Prefilling of syringes for self-administration of insulin or other medications is considered to be assistance with medications that are ordinarily self-administered and is an appropriate *home health aide service*.

However, ***where state law requires*** that a licensed nurse prefill syringes, a skilled nursing visit to prefill syringes is paid as a skilled nursing visit (if the patient otherwise needs skilled nursing care, physical therapy, or speech-language pathology services), but is not considered to be a skilled nursing service.

40.1.2.4 Oral and Topical Routes

Oral Medications

The **administration of oral medications by a nurse is not reasonable and necessary skilled nursing** care except in the specific situation in which the complexity of the patient's condition, the nature of the drugs prescribed, and the number of drugs prescribed require the skills of a licensed nurse to detect and evaluate side effects or reactions. The medical record must document the specific circumstances that cause administration of an oral medication to require skilled observation and assessment.

Eye Drops and Topical Ointments

The **administration of eye drops and topical ointments does not require the skills of a nurse.** Therefore, even if the administration of eye drops or ointments is necessary to the treatment of an illness or injury and the patient cannot self-administer the drops, and there is no one available to administer them, the visits cannot be covered as a skilled nursing service. This section does not eliminate coverage for skilled nursing visits for observation and assessment of the patient's condition.

Nursing Medication Administration: Key Considerations

- Very limited ability to give oral medication as covered service
- Limited ability to give topical medication as covered service
- Very limited ability to give subcutaneous (SC/SQ) injections
- May give intramuscular (IM) injections
- B_{12} has diagnosis parameters for coverage
- Insulin most common injection, but must establish caregiver status, patient self-injection status, and support daily nursing care (non-intermittent)
- Other non-insulin injectables can support nursing but caregiver status/living arrangement/pre-fill options must be addressed

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40.1.2.7 Catheters

Insertion and sterile irrigation and replacement of catheters, care of a suprapubic catheter, and in selected patients, urethral catheters, are considered to be skilled nursing services.

Where the catheter is necessitated by a permanent or temporary loss of bladder control, skilled nursing services that are provided at a frequency appropriate to the type of catheter in use would be considered reasonable and necessary.

Absent complications**, Foley catheters generally require skilled care once approximately every 30 days** and silicone catheters generally require skilled care once every 60-90 days and this frequency of service would be considered reasonable and necessary.

However, where there are complications that require more frequent skilled care related to the catheter, such care would, with adequate documentation, be covered.

40.1.2.7 Urinary Catheters: Key Considerations

- Generally is covered as skilled due to nature of procedure
- Frequency of change is limited (+PRN visits)
- Requires documentation of catheter type, balloon size, frequency of change
- Specify if indwelling or suprapubic
- Diagnosis of urinary dysfunction needed to support

40.1.2.8 Wound Care

Care of wounds, (including, but not limited to, ulcers, burns, pressure sores, open surgical sites, fistulas, tube sites, and tumor erosion sites) is considered to be a skilled nursing service.

For skilled nursing care to be reasonable and necessary to treat a wound, the size, depth, nature of drainage (color, odor, consistency, and quantity), and condition and appearance of the skin surrounding the wound must be documented in the clinical findings so that an assessment of the need for skilled nursing care can be made.

This includes whether wound care is performed via dressing changes…Coverage or denial of skilled nursing visits for wound care may not be based solely on the stage classification of the wound, but rather must be based on all of the documented clinical findings.

Moreover, the plan of care must contain the specific instructions for the treatment of the wound.

Where the physician has ordered appropriate active treatment (e.g., sterile or complex dressings, NPWT [negative pressure], administration of prescription medications, etc.) of wounds with specified characteristics, the skills of a licensed nurse are usually reasonable and necessary for treatment of:

40.1.2.8 Wound Types Supporting Care

- Open wounds which are draining purulent or colored exudate or have a foul odor present or for which the patient is receiving antibiotic therapy;
- Wounds with a drain or T-tube that require shortening or movement of such drains;
- Wounds which require irrigation or instillation of a sterile cleansing or medicated solution into several layers of tissue and skin and/or packing with sterile gauze;
- Recently debrided ulcers;
- Pressure sores (decubitus ulcers) with the following characteristics:
  - There is partial tissue loss with signs of infection such as foul odor or purulent drainage; or
  - There is full thickness tissue loss that involves exposure of fat or invasion of other tissue such as muscle or bone.
- **NOTE: Wounds or ulcers that show redness, edema, and induration, at times with epidermal blistering or desquamation do not ordinarily require skilled nursing care.**
- Wounds with exposed internal vessels or a mass that may have a proclivity for hemorrhage when a dressing is changed (e.g., post radical neck surgery, cancer of the vulva);

40.1.2.8 More wound types supporting care

- Open wounds or widespread skin complications following radiation therapy, or which result from immune deficiencies or vascular insufficiencies;
- Post-operative wounds where there are complications such as infection or allergic reaction or where there is an underlying disease that has a reasonable potential to adversely affect healing (e.g., diabetes);
- Third degree burns, and second degree burns where the size of the burn or presence of complications causes skilled nursing care to be needed;
- Skin conditions that require application of nitrogen mustard or other chemotherapeutic medication that present a significant risk to the patient;
- Other open or complex wounds that require treatment that can only be provided safely and effectively by a licensed nurse.

40.1.2.8 Wound Care: Key Considerations

- Wound care must be complex (more than skin breakdown or open)
- Care cannot be safely performed by non-medical person
- Plan of care must contain details of ordered treatment
- If daily care, must establish a reasonable and finite end of daily care date (if daily care over 3 weeks in length)
- Post-operative wounds must still have complications or underlying disease that impair healing
- Simple presence of a wound does not result in coverage

40.1.2.13 Venipuncture

Venipuncture for the purposes of obtaining a blood sample cannot be the sole reason for Medicare home health eligibility.

However, if a beneficiary qualifies for home health eligibility based on a skilled need other than solely venipuncture, medically reasonable and necessary venipuncture may be covered.

For venipuncture to be reasonable and necessary:

1. The physician order for the venipuncture for a laboratory test should be associated with a specific symptom or diagnosis, or the documentation should clarify the need for the test when it is not diagnosis/illness specific. In addition, the treatment must be recognized (in the Physician's Desk Reference, or other authoritative source) as being reasonable and necessary to the treatment of the illness or injury for venipuncture and monitoring the treatment must also be reasonable and necessary.
2. The frequency of testing should be consistent with accepted standards of medical practice for continued monitoring of a diagnosis, medical problem, or treatment regimen. Even where the laboratory results are consistently stable, periodic venipuncture may be reasonable and necessary because of the nature of the treatment.
3. The home health record must document the rationale for the blood draw as well as the results.

40.1.2.13 Monitoring

Examples of reasonable and necessary venipuncture for stabilized patients include:

a. **Captopril** may cause side effects such as leukopenia and agranulocytosis and it is standard medical practice to monitor the white blood cell count and differential count on a routine basis (every 3 months) when the results are stable and the patient is asymptomatic.

b. In monitoring **phenytoin (e.g., Dilantin) administration**, the difference between a therapeutic and a toxic level of phenytoin in the blood is very slight and it is therefore appropriate to monitor the level on a routine basis (every 3 months) when the results are stable and the patient is asymptomatic.

c. Venipuncture for **fasting blood sugar (FBS)**

- An unstable insulin dependent or noninsulin dependent diabetic would require FBS more frequently than once per month if ordered by the physician.
- Where there is a new diagnosis or where there has been a recent exacerbation, but the patient is not unstable, monitoring once per month would be reasonable and necessary.
- A stable insulin or noninsulin dependent diabetic would require monitoring every 2-3 months.

d. Venipuncture for prothrombin (PT)

- Where the documentation **shows that the dosage is being adjusted**, monitoring would be reasonable and necessary as ordered by the physician.
- Where the results are stable within the therapeutic ranges, monthly monitoring would be reasonable and necessary.
- Where the results remain within nontherapeutic ranges, there must be specific documentation of the factors that indicate why continued monitoring is reasonable and necessary.

Venipuncture: Key Considerations

- Cannot be the sole nursing skill provided
- Medication for which labs are drawn must show variance in therapeutic levels (once stability is obtained no longer covered—or covered at lower frequency)
- Must show that patient cannot have labs drawn with physician office visit or at outpatient lab

40.1.2.15 Psychiatric Evaluation, Therapy, and Teaching

The evaluation, psychotherapy, and teaching needed by a patient suffering from a **diagnosed psychiatric disorder** that requires active treatment by a psychiatrically trained nurse.

Psychiatrically trained nurses have special training and/or experience beyond the standard curriculum required for a registered nurse. The services of the psychiatric nurse are to be provided under a plan of care established and reviewed by a physician.

Psychiatric nursing must be furnished by an agency that does not primarily provide care and treatment of mental diseases.

Services of a psychiatric nurse would **not be considered reasonable and necessary** to assess or monitor use of psychoactive drugs that are being used for non-psychiatric diagnoses or **to monitor the condition of a patient with a known psychiatric illness who is on treatment but is considered stable**. A person on treatment would be considered stable if their symptoms were absent or minimal or if symptoms were present but were relatively stable and did not create a significant disruption in the patient's normal living situation.

40.1.2.15: Key Considerations

- Must be performed by nurse with psychiatric qualifications (PGBA LCD L34561)
- Psychiatric nurse should address ALL patient nursing needs - not just the psychiatric issues
- Dementia is NOT a psychiatric condition
- Makes homebound documentation more important
- Psychiatric diagnosis/condition must be showing changes or instability to support medication monitoring/assistance

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Section 40.2.1

General Principles Governing Reasonable and Necessary Physical Therapy, Speech-Language Pathology Services, and Occupational Therapy

40.2.1 Therapy Medical Necessity

A service that is ordinarily considered unskilled could be considered a skilled therapy service in cases where there is clear documentation that, because of special medical complications, skilled rehabilitation personnel are required to perform the service.

The skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury within the context of the patient's unique medical condition.

a. The services must be consistent with the nature and severity of the illness or injury, the patient's particular medical needs, including the requirement that the amount, frequency, and duration of the services must be reasonable; and
b. The services must be considered, under accepted standards of medical practice, to be specific, safe, and effective treatment for the patient's condition, meeting the standards noted below. The home health record must specify the purpose of the skilled service provided.

To ensure therapy services are effective, at defined points during a course of treatment, for each therapy discipline for which services are provided, a qualified therapist (instead of an assistant) must perform the ordered therapy service.

During this visit, the therapist must assess the patient using a method which allows for objective measurement of function and successive comparison of measurements.

The therapist must document the measurement results in the clinical record.

40.2.1 Therapy Assessments

Initial Therapy Assessment

- For each therapy discipline for which services are provided, a qualified therapist (instead of an assistant) must assess the patient's function using a method which **objectively measures** activities of daily living such as, but not limited to, eating, swallowing, bathing, dressing, toileting, walking, climbing stairs, using assistive devices, and mental and cognitive factors. The measurement results must be documented in the clinical record.
- Where more than one discipline of therapy is being provided, a qualified therapist from each of the disciplines must functionally assess the patient. The therapist must document the measurement results which correspond to the therapist's discipline and care plan goals in the clinical record.

40.2.1 Therapy Reassessments

- At least once every 30 days, for each therapy discipline for which services are provided, a qualified therapist (instead of an assistant) must provide the ordered therapy service, functionally reassess the patient, **and compare the resultant measurement to prior assessment measurements.** The therapist must document in the clinical record the results along with the therapist's determination of the effectiveness of therapy, or lack thereof.

- For multi-discipline therapy cases, a qualified therapist from each of the disciplines must functionally reassess the patient. The therapist must document the measurement results which correspond to the therapist's discipline and care plan goals in the clinical record.

- The 30-day clock begins with the first therapy service (of that discipline) and the clock resets with each therapist's visit/assessment/measurement/documentation (of that discipline).

- **Services involving activities for the general welfare of any patient, e.g., general exercises to promote overall fitness or flexibility and activities to provide diversion or general motivation do not constitute skilled therapy. Unskilled individuals without the supervision of a therapist can perform those services.**

40.2.1 Restoration of Function

For therapy services to be covered **one of the following three** conditions must be met:

1. The skills of a qualified therapist are needed to **restore patient function**:
   - To meet this coverage condition the therapy services must be provided with the expectation that the condition of the patient will improve materially in a reasonable and generally predictable period of time. Improvement is evidenced by objective successive measurements.
   - Therapy is not considered reasonable and necessary under this condition if the patient's expected restorative potential would be insignificant in relation to the extent and duration of therapy services required to reach such potential.
   - Therapy is **not required to effect improvement or restoration of function where a patient suffers a transient or easily reversible loss of function** (such as temporary weakness following surgery) which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Therapy in such cases is not considered reasonable and necessary to treat the patient's illness or injury, under this condition.

   However, if the criteria for maintenance therapy described in (3) below is met, therapy could be covered under that condition.

40.2.1 Establishing a Maintenance Plan

2. The patient's clinical condition requires the specialized skills, knowledge, and judgment of a qualified therapist **to establish or design a maintenance program**, related to the patient's illness or injury, in order to ensure the safety of the patient and the effectiveness of the program.

For patients receiving **rehabilitative/restorative** therapy services **the expectation is that the development of that maintenance program would occur during the last visit(s) for rehabilitative/restorative treatment. The goals of a maintenance program** would be to maintain the patient's current functional status or to prevent or slow further deterioration.

Necessary periodic reevaluations by a qualified therapist of the beneficiary and maintenance program are covered if the specialized skills, knowledge, and judgment of a qualified therapist are required.

Where a maintenance program is not established until after the rehabilitative/restorative therapy program has been completed or where there was no rehabilitative/restorative therapy program, the therapist must document why the maintenance program could not be developed during those last rehabilitative/restorative treatment visit(s).

When designing or establishing a maintenance program, the qualified **therapist must teach the patient or the patient's family or caregiver's necessary techniques, exercises or precautions as necessary to treat the illness or injury**. Visits made by skilled therapists to a patient's home solely to train other home health agency staff (e.g., home health aides) are not billable as visits since the home health agency is responsible for ensuring that its staff is properly trained to perform any service it furnishes. The cost of a skilled therapist's visit for the purpose of training home health agency staff is an administrative cost to the agency.

40.2.1 Performing a Maintenance Plan

3. The skills of a qualified therapist (not an assistant) are needed to **perform maintenance therapy**:

- Coverage of therapy services to perform a maintenance program is not determined solely on the presence or absence of a beneficiary's potential for improvement from the therapy, but rather on the beneficiary's need for skilled care. Such a **maintenance program to maintain the patient's current condition or to prevent or slow further deterioration is covered** so long as the beneficiary requires skilled care for the safe and effective performance of the program. When, however, the individualized assessment does not demonstrate such a necessity for skilled care, including when the performance of a maintenance program does not require the skills of a therapist because it could safely and effectively be accomplished by the patient or with the assistance of non-therapists, including unskilled caregivers, such maintenance services will not be covered.
- Further, under the standard set forth in the previous paragraph, skilled care is necessary for the performance of a safe and effective maintenance program only when (a) the particular patient's special medical complications require the skills of a qualified therapist to perform a therapy service that would otherwise be considered non-skilled; or (b) the needed therapy procedures are of such complexity that the skills of a qualified therapist are required to perform the procedure.

40.2.1 Therapy Visit Note Content

As is outlined in home health regulations and the home health agency Conditions of Participation (CoPs), the clinical record of the patient must contain progress and clinical notes. **It is expected that the home health records for every visit will reflect the need for the skilled medical care provided.** These clinical notes are also expected to provide important communication among all members of the home care team regarding the development, course and outcomes of the skilled observations, assessments, treatment and training performed. The clinical notes are expected to tell the story of the patient's achievement towards his/her goals as outlined in the Plan of Care. In this way, the notes will serve to demonstrate why a skilled service is needed.

Therefore, the home health clinical notes must document as appropriate:

- The history and physical exam pertinent to the day's visit , (including the response or changes in behavior to previously administered skilled services) and
- The skilled services applied on the current visit, and
- The patient/caregiver's immediate response to the skilled services provided, and
- The plan for the next visit based on the rationale of prior results.

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40.2.1 Therapy Visit Note Measurements and Requirements

Clinical notes should be written so that they adequately describe the reaction of a patient to his/her skilled care. Clinical notes should also provide a clear picture of the treatment, as well as "next steps" to be taken. Vague or subjective descriptions of the patient's care should not be used. For example terminology such as the following would not adequately describe the need for skilled care:

- Patient tolerated treatment well
- Caregiver instructed in medication management
- Continue with POC

Objective measurements of physical outcomes of treatment should be provided and/or a clear description of the changed behaviors due to education programs should be recorded in order that all concerned can follow the results of the applied services.

When the skilled service is being provided to either maintain the patient's condition or prevent or slow further deterioration, the clinical notes must also describe:

- A detailed rationale that explains the need for the skilled service in light of the patient's overall medical condition and experiences,
- The complexity of the service to be performed, and
- Any other pertinent characteristics of the beneficiary or home.

Skilled Therapy: Key Considerations

- Restorative or maintenance service
- Objective/measurable baseline findings
- Objective successive measurements
- Comparison of successive findings
- More than just teachable exercises
- Addresses more than ambulation, strength, endurance
- Changes in condition resulting from therapy interventions are documented
- Prior level of function identified for restorative plans
- Goal focused: progress towards, rehab potential
- Need for therapy intervention is documented (beyond HEP)
- More than for “general welfare”

Medicare Program Integrity Manual (PIM)

- Internet-Only Manual (IOM), Publication 100-08
- Chapter 3: Verifying Potential Errors and Taking Corrective Actions
- Chapter 6: Medicare Contractor Medical Review Guidelines for Specific Services

100-08, Ch 3; §3.3.2.1- Progress Notes and Templates

B. Guidelines Regarding Which Documents Review Contractors Will Consider

- The review contractor shall consider all medical record entries made by physicians and LCMPs [licensed certified medical professional]. See PIM 3.3.2.5 regarding consideration of Amendments, Corrections and Delayed Entries in Medical Documentation.
- The amount of necessary clinical information needed to demonstrate that all coverage and coding requirements are met will vary depending on the item/service. See the applicable National and Local Coverage Determination for further details.
- ***Some templates provide limited options and/or space for the collection of information such as by using "check boxes," predefined answers, limited space to enter information, etc. CMS discourages the use of such templates. Claim review experience shows that that limited space templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met.***
- …be aware that templates designed to gather selected information focused primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. This is often because these documents generally do not provide sufficient information to adequately show that the medical necessity criteria for the item/service are met.

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Recap

- MBPM, Chapter 7 Sections
- 30.1.1 Homebound
- 40.1.1 Nursing Services
- 40.1.2.1 Nursing Observation & Assessment
- 40.1.2.2 Management & Evaluation
- 40.1.2.3 Teaching & Training

- MPBM Chapter 7, Sections
- 40.1.2.4 Medication Administration
- 40.1.2.7 Catheters
- 40.1.2.8 Wound Care
- 40.1.2.13 Venipuncture
- 40.1.2.15 Psychiatric Nursing
- 40.2.1 Therapy Services

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Conclusion

- Clinician knowledge of the regulations is first step to achieving compliance
- Clinician implementation of regulatory requirements is key to achieving compliance
- The right charting produces the right outcome

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Questions?

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