CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 233	**Date: February 24, 2017**
	Change Request 9898

SUBJECT: Clarification of Payment Policy Changes for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device and the Outlier Payment Methodology for Home Health Services

I. SUMMARY OF CHANGES: This Change Request manualizes policies discussed in the CY 2017 HH PPS Final Rule published on November 3, 2016. These polices relate to payment for furnishing of NPWT using a disposable device as well as changes to the methodology used to calculate outlier payments to HHAs.

EFFECTIVE DATE: January 1, 2017
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 27, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	7/Table of Contents
R	7/10.1/National 60-Day Episode Rate
R	7/10.9/Outlier Payments
R	7/10.11/Consolidated Billing
R	7/30.1.1/Patient Confined to the Home
R	7/30.2.10/Sequence of Qualifying Services and Other Medicare Covered Home Health Services
R	7/30.4/Needs Skilled Nursing Care on an Intermittent Basis (Other than Solely Venipuncture for the Purposes of Obtaining a Blood Sample), Physical Therapy, Speech-Language Pathology Services, or Has Continued Need for Occupational Therapy
R	7/30.5.1/Physician Certification
R	7/30.5.1.2/Supporting Documentation Requirements

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	7/40.1.2.8/Wound Care
R	7/50.4/Medical Supplies (Except for Drugs and Biologicals Other Than Covered Osteoporosis Drugs), the Use of Durable Medical Equipment and Furnishing Negative Pressure Wound Therapy Using a Disposable Device
N	7/50.4.4/Negative Pressure Wound Therapy Using a Disposable Device
R	7/60.4/Coinsurance, Copayments, and Deductibles

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 233	Date: February 24, 2017	Change Request: 9898

SUBJECT: Clarification of Payment Policy Changes for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device and the Outlier Payment Methodology for Home Health Services

EFFECTIVE DATE: January 1, 2017
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I. GENERAL INFORMATION

A. Background: In the calendar year (CY) 2017 Home Health Prospective Payment System (HH PPS) final rule (81 FR 76702), CMS finalized clarifications and revisions to policies related to payment for furnishing of NPWT using a disposable device as well as changes to the methodology used to calculate outlier payments to HHAs. In the CY 2015 HH PPS final rule (79 FR 66032), CMS finalized changes to the physician certification of patient eligibility for the Medicare home health benefit as well as the supporting documentation needed to substantiate a patient's eligibility for the benefit attested to by the certifying physician.

B. Policy: The Consolidated Appropriations Act, 2016 (Pub. L. 114-113) requires a separate payment to be made to Home Health Agencies (HHAs) for a disposable NPWT device when furnished, on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. As such, CMS finalized policies related to payment for furnishing NPWT using a disposable device in order to implement section 504 of the Consolidated Appropriations Act, 2016. CMS also finalized a change in the methodology used to calculate outlier payments, moving from a cost per visit approach to a cost per unit approach (1 unit = 15 minutes), effective January 1, 2017. This approach more accurately reflects the cost of an outlier episode of care and thus better aligns outlier payments with episode costs than the cost-per-visit approach. Chapter 7 of Pub. 100-02 Medicare Benefit Policy Manual has been revised to reflect the changes in payment for furnishing NPWT using a disposable device as well as the change in calculating the cost for an episode of care when determining whether an episode will receive an outlier payment.

Also included in this update to Chapter 7, are clarifications pertaining to existing policies. Specifically, a clarification was added to section 30.1.1 to provide additional guidance on determining whether a patient meets the longstanding statutory definition of "confined to the home" or "homebound", which is one of several conditions that the patient must meet to be eligible for Medicare home health services. In addition, in section 30.5.1, example language has been included that would satisfy the physician certification requirements. In section 30.5.1.2, clarifications to the supporting documentation requirements implemented January 1, 2015 and outlined in the CY 2015 HH PPS final rule have been added.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9898.1	Medicare contractors shall be aware of the revisions to policies related to payment for furnishing of Negative Pressure Wound Therapy (NPWT) using a disposable device as well as changes to the methodology used to calculate outlier payments to HHAs.			X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9898.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.			X		

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
9898.1	CR 9736 contains the related implementation and systems requirements, including the addition of Pub. 100-04, Medicare Claims Processing Manual, chapter 10, Section 90.3 – Billing Instructions for Disposable Negative Pressure Wound Therapy Services.

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Hillary Loeffler, 410-786-0456 or hillary.loeffler@cms.hhs.gov, Laura Ashbaugh, 410-786-1113 or laura.ashbaugh@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Benefit Policy Manual
Chapter 7 - Home Health Services

Table of Contents
(Rev. 233, Issued: 02-24-17)

10.1 - National 60-Day Episode Rate

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

A. Services Included

The law requires the 60-day episode to include all covered home health services, including medical supplies, paid on a reasonable cost basis. That means the 60-day episode rate includes costs for the six home health disciplines and the costs for routine and nonroutine medical supplies. The six home health disciplines included in the 60-day episode rate are:

1. Skilled nursing services;
2. Home health aide services;
3. Physical therapy;
4. Speech-language pathology services;
5. Occupational therapy services; and
6. Medical social services.

The 60-day episode rate also includes amounts for nonroutine medical supplies and therapies that could have been unbundled to Part B prior to HH PPS. (See §10.11.C for those services.)

B. Excluded Services

The law specifically excludes durable medical equipment (DME) from the 60-day episode rate and consolidated billing requirements. DME continues to be paid on the fee schedule outside of the HH PPS rate.

The osteoporosis drug (injectable calcitonin), which is covered where a woman is postmenopausal and has a bone fracture. This drug is also excluded from the 60-day episode rate but must be billed by the home health agency (HHA) while a patient is under a home health plan of care since the law requires consolidated billing of osteoporosis drugs. The osteoporosis drug continues to be paid on a reasonable cost basis.

Negative pressure wound therapy (NPWT) using a disposable device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy (in lieu of a conventional NPWT DME system), is also excluded from the 60-day episode rate, but must be billed by the home health agency (HHA) while a patient is under a home health plan of care since the law requires consolidated billing of NPWT using a disposable device.

Furnishing NPWT using a disposable device means the application of a new applicable disposable device, as that term is defined in §1834 of the Social Security Act (the Act), which includes the professional services (specified by the assigned CPT code) that are provided.

10.9 - Outlier Payments

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

When cases experience an unusually high level of services in a 60-day period, Medicare systems will provide additional or "outlier" payments to the case-mix and wage-adjusted episode payment. Outlier payments can result from medically necessary high utilization in any or all-home health service disciplines. CMS makes

outlier payments when the cost of care exceeds a threshold dollar amount. The outlier threshold for each case-mix group is the episode payment amount for that group or the PEP adjustment amount for the episode, plus a fixed dollar loss amount, which is the same for all case-mix groups. The outlier payment is a proportion of the amount of imputed costs beyond the threshold. CMS calculates the imputed cost for each episode by *first taking* the national per-visit *payment amounts* for each discipline and calculating per-unit payment amounts (1 unit = 15 minutes). *The per-unit amounts are then multiplied* by the number of *units* in the discipline and computing the total imputed cost for all disciplines *(summed across the six disciplines of care).*

If the imputed cost for the episode is greater than the sum of the case-mix and wage-adjusted episode payment plus the fixed dollar loss amount (the outlier threshold), a set percentage (the loss sharing ratio) of the difference between the imputed amount and outlier threshold will be paid to the HHA as a wage-adjusted outlier payment in addition to the episode payment.

The amount of the outlier payment is determined as follows:

1. Calculate the case-mix and wage-adjusted episode payment (including non-routine supplies (NRS));

2. Add the wage-adjusted fixed dollar loss amount. The sum of steps 1 and 2 is the outlier threshold for the episode;

3. Calculate the wage-adjusted imputed cost of the episode by first multiplying the total number of *units* for each home health discipline by the national per *unit* amounts, and wage-adjusting those amounts. Sum the per discipline wage-adjusted imputed amounts to yield the total wage-adjusted imputed cost for the episode;

4. Subtract the total imputed cost for the episode (total from Step 3) from the sum of the case-mix and wage-adjusted episode payment and the wage-adjusted fixed dollar loss amount (sum of Steps 1 and 2 - outlier threshold);

5. Multiply the difference by the loss sharing ratio; and

6. That total amount is the outlier payment for the episode.

Effective January 1, 2010, an outlier cap precludes any HHA from receiving more than 10 percent of their total home health payment in outliers.

10.11 - Consolidated Billing

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

For individuals under a home health plan of care, payment for all services and supplies, with the exception of osteoporosis drugs, DME, *and furnishing NPWT using a disposable device* is included in the HH PPS base payment rates. HHAs must provide the covered home health services (except DME) either directly or under arrangement, and must bill for such covered home health services.

Payment must be made to the HHA.

A. Home Health Services Subject to Consolidated Billing Requirements

The home health services included in the consolidated billing governing the HH PPS are:

- Part-time or intermittent skilled nursing services;

- Part-time or intermittent home health aide services;
- Physical therapy;
- Speech-language pathology services;
- Occupational therapy;
- Medical social services;
- Routine and nonroutine medical supplies;
- Covered osteoporosis drug as defined in §1861(kk) of the Act, but excluding other drugs and biologicals;
- *Furnishing NPWT using a disposable device as that term is defined in §1834 of the Act, which includes the professional services (specified by the assigned CPT code) that are provided;*
- Medical services provided by an intern or resident-in-training of the program of the hospital in the case of an HHA that is affiliated or under common control with a hospital with an approved teaching program; and
- Home health services defined in §1861(m) *of the Act* provided under arrangement at hospitals, SNFs, or rehabilitation centers when they involve equipment too cumbersome to bring to the home or are furnished while the patient is at the facility to receive such services.

B. Medical Supplies

The law requires that all medical supplies (routine and nonroutine) be provided by the HHA while the patient is under a home health plan of care. The agency that establishes the episode is the only entity that can bill and receive payment for medical supplies during an episode for a patient under a home health plan of care. Both routine and nonroutine medical supplies are included in the base rates for every Medicare home health patient regardless of whether or not the patient requires medical supplies during the episode.

Due to the consolidated billing requirements, CMS provided additional amounts in the base rates for those nonroutine medical supplies that have a duplicate Part B code that could have been unbundled to Part B prior to HH PPS. See §50.4 for detailed discussion of medical supplies.

Medical supplies used by the patient, provider, or other practitioners under arrangement on behalf of the agency (other than physicians) are subject to consolidated billing and bundled into the HHA episodic payment rate. Once a patient is discharged from home health and not under a home health plan of care, the HHA is not responsible for medical supplies.

DME, including supplies covered as DME, are paid separately from the HH PPS and are excluded from the consolidated billing requirements governing the HH PPS. The determining factor is the medical classification of the supply, not the diagnosis of the patient. For example, infusion therapy will continue to be covered under the DME benefit separately and excluded from the consolidated billing requirements governing the HH PPS. DME supplies that are currently covered and paid in accordance with the DME fee schedule as category SU are billed under the DME benefit.

The osteoporosis drug (injectable calcitonin) is included in consolidated billing under the home health benefit. However, payment is not bundled into the HH PPS payment rates. HHAs must bill for the osteoporosis drug in accordance with billing instructions. Payment is in addition to the HH PPS payment.

Furnishing NPWT using a disposable device is included in consolidated billing under the home health benefit. However, payment is not bundled into the HH PPS payment rates. HHAs must bill for NPWT using a disposable device in accordance with billing instructions. Payment is in addition to the HH PPS payment.

C. Relationship Between Consolidated Billing Requirements and Part B Supplies and Part B Therapies Included in the Baseline Rates That Could Have Been Unbundled Prior to HH PPS That No Longer Can Be Unbundled

The HHA is responsible for the services provided under arrangement on their behalf by other entities. Covered home health services at §1861(m) of the Act (except DME) are included in the baseline HH PPS rates and subject to the consolidated billing requirements while the patient is under a plan of care of the HHA. The time the services are bundled is while the patient is under a home health plan of care.

Physician services or nurse practitioner services paid under the physician fee schedule are not recognized as home health services included in the PPS rates. Supplies incident to a physician service or related to a physician service billed to the Medicare contractor are not subject to the consolidated billing requirements. The physician would not be acting as a supplier billing the DME Medicare contractor in this situation.

Therapies (physical therapy, occupational therapy, and speech-language pathology services) are covered home health services that are included in the baseline rates and subject to the consolidated billing requirements. In addition to therapies that had been paid on a cost basis under home health, CMS has included in the rates additional amounts for Part B therapies that could have been unbundled prior to PPS. These therapies are subject to the consolidated billing requirements. There are revenue center codes that reflect the ranges of outpatient physical therapy, occupational therapy, and speech-language pathology services and Healthcare Common Procedure Coding System (HCPCS) codes that reflect physician supplier codes that are physical therapy, occupational therapy, and speech-language pathology services by code definition and are subject to the consolidated billing requirements. Therefore, the above-mentioned therapies must be provided directly or under arrangement on behalf of the HHA while a patient is under a home health plan of care and cannot be separately billed to Part B during an open 60-day episode.

D. Freedom of Choice Issues

A beneficiary exercises his or her freedom of choice for the services under the home health benefit listed in §1861(m) of the Act, including medical supplies, but excluding DME covered as a home health service by choosing the HHA. Once a home health patient chooses a particular HHA, he or she has clearly exercised freedom of choice with respect to all items and services included within the scope of the Medicare home health benefit (except DME). The HHA's consolidated billing role supersedes all other billing situations the beneficiary may wish to establish for home health services covered under the scope of the Medicare home health benefit during the certified episode.

E. Knowledge of Services Arranged for on Behalf of the HHA

The consolidated billing requirements governing HH PPS requires that the HHA provide all covered home health services (except DME) either directly or under arrangement while a patient is under a home health plan of care. Providing services either directly or under arrangement requires knowledge of the services provided during the episode. In addition, in accordance with current Medicare conditions of participation and Medicare coverage guidelines governing home health, the patient's plan of care must reflect the physician ordered services that the HHA provides either directly or under arrangement. An HHA would not be responsible for payment in

the situation in which they have no prior knowledge (unaware of physician orders) of the services provided by an entity during an episode to a patient who is under their home health plan of care. An HHA is responsible for payment in the situation in which services are provided to a patient by another entity, under arrangement with the HHA, during an episode in which the patient is under the HHA's home health plan of care. However, it is in the best interest of future business relationships to discuss the situation with any entity that seeks payment from the HHA during an episode in an effort to resolve any misunderstanding and avoid such situations in the future.

30.1.1 - Patient Confined to the Home

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

For a patient to be eligible to receive covered home health services under both Part A and Part B, the law requires that a physician certify in all cases that the patient is confined to his/her home. For purposes of the statute, 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 one of the *criterion one* conditions, then the patient must ALSO meet two additional requirements defined in *criterion two* below.

2. *Criterion Two*:

- There must exist a normal inability to leave home;

AND

- Leaving home must require a considerable and taxing effort.

To clarify, in determining whether the patient meets criterion two of the homebound definition, the clinician needs to take into account the illness or injury for which the patient met criterion one and consider the illness or injury in the context of the patient's overall condition. The clinician is not required to include standardized phrases reflecting the patient's condition (e.g., repeating the words "taxing effort to leave the home") in the patient's chart, nor are such phrases sufficient, by themselves, to demonstrate that criterion two has been met. For example, 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 clinical information about the patient's overall health status may include, but is not limited to, such factors as the patient's diagnosis, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, etc.

If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need

to receive health care treatment. Absences attributable to the need to receive health care treatment include, but are not limited to:

- Attendance at adult day centers to receive medical care;
- Ongoing receipt of outpatient kidney dialysis; or
- The receipt of outpatient chemotherapy or radiation therapy.

Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a state, or accredited to furnish adult day-care services in a state, shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of an infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. It is expected that in most instances, absences from the home that occur will be for the purpose of receiving health care treatment. However, occasional absences from the home for nonmedical purposes, e.g., an 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 would not necessitate a finding that the patient is not homebound if the absences are undertaken on an infrequent basis or are 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.

Some examples of homebound patients that illustrate the factors used to determine whether a homebound condition exists are listed below.

- A patient paralyzed from a stroke who is confined to a wheelchair or requires the aid of crutches in order to walk.
- A patient who is blind or senile and requires the assistance of another person in leaving their place of residence.
- A patient who has lost the use of their upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and requires the assistance of another individual to leave their place of residence.
- A patient in the late stages of ALS or neurodegenerative disabilities. In determining whether the patient has the general inability to leave the home and leaves the home only infrequently or for periods of short duration, it is necessary (as is the case in determining whether skilled nursing services are intermittent) to look at the patient's condition over a period of time rather than for short periods within the home health stay. For example, a patient may leave the home (meeting both criteria listed above) more frequently during a short period when the patient has multiple appointments with health care professionals and medical tests in 1 week. So long as the patient's overall condition and experience is such that he or she meets these qualifications, he or she should be considered confined to the home.
- A patient who has just returned from a hospital stay involving surgery, who may be suffering from resultant weakness and pain because of the surgery and; therefore, their actions may be restricted by their physician to certain specified and limited activities (such as getting out of bed only for a specified period of time, walking stairs only once a day, etc.).
- A patient with arteriosclerotic heart disease of such severity that they must avoid all stress and physical activity.

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

The aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age would not be considered confined to the home for purposes of receiving home health services unless they meet one of the above conditions.

Although a patient must be confined to the home to be eligible for covered home health services, some services cannot be provided at the patient's residence because equipment is required that cannot be made available there. If the services required by an individual involve the use of such equipment, the HHA may make arrangements with a hospital, SNF, or a rehabilitation center to provide these services on an outpatient basis. (See §50.6.) However, even in these situations, for the services to be covered as home health services 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 HHA will be requested to furnish the Medicare contractor with the information necessary to establish that the patient is homebound as defined above.

30.2.10 - Sequence of Qualifying Services and Other Medicare Covered Home Health Services

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

Once patient eligibility has been confirmed and the plan of care contains physician orders for the qualifying service as well as other Medicare covered home health services, the qualifying service does not have to be rendered prior to the other Medicare covered home health services ordered in the plan of care. The sequence of visits performed by the disciplines must be dictated by the individual patient's plan of care. For example, for an eligible patient in an initial 60-day episode that has both physical therapy and occupational therapy orders in the plan of care, the sequence of the delivery of the type of therapy is irrelevant as long as the need for the qualifying service is established prior to the delivery of other Medicare covered services and the qualifying discipline provides a billable visit prior to transfer or discharge in accordance with 42 CFR 409.43(f).

NOTE: Dependent services provided after the final qualifying skilled service are not covered under the home health benefit, except when the dependent service was *not* followed by a qualifying skilled service *due to* unexpected inpatient admission, death of the patient, or some other unanticipated event.

30.4 - Needs Skilled Nursing Care on an Intermittent Basis (Other than Solely Venipuncture for the Purposes of Obtaining a Blood Sample), Physical Therapy, Speech-Language Pathology Services, or Has Continued Need for Occupational Therapy

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

The patient must need one of the following types of services:

1. Skilled nursing care that is

    - Reasonable and necessary as defined in §40.1;

    - Needed on an "intermittent" *basis* as defined in §40.1.*3*; and

    - Not solely needed for venipuncture for the purposes of obtaining blood sample as defined in §40.1.2.13;or

2. Physical therapy as defined in §40.2.2; or

3. Speech-language pathology services as defined in §40.2.3; or

4. Have a continuing need for occupational therapy as defined in §§40.2.4.

The patient has a continued need for occupational therapy when:

1. The services which the patient requires meet the definition of "occupational therapy" services of §40.2.*4*, and

2. The patient's eligibility for home health services has been established by virtue of a prior need for skilled nursing care (other than solely venipuncture for the purposes of obtaining a blood sample), speech-language pathology services, or physical therapy in the current or prior certification period.

EXAMPLE: A patient who is recovering from a cerebrovascular accident (CVA) has an initial plan of care that called for physical therapy, speech-language pathology services, *occupational therapy,* and home health aide services. In the next certification period, the physician orders only occupational therapy and home health aide services because the patient no longer needs the skills of a physical therapist or a speech-language pathologist, but needs the services provided by the occupational therapist. The patient's need for occupational therapy qualifies him for home health services, including home health aide services (presuming that all other qualifying criteria are met), *because in the prior certification period the beneficiary's eligibility for home health services was established by virtue of prior needs for physical therapy and speech-language pathology, and occupational therapy was initiated while the patient still required physical therapy and/or speech language-pathology.*

30.5.1 - Physician Certification

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

A certification (versus recertification) is considered to be anytime that a Start of Care OASIS is completed to initiate care. In such instances, a physician must certify (attest) that:

1. The home health services are or were needed because the patient is or was confined to the home as defined in §30.1.*1*;

2. The patient needs or needed skilled nursing services on an intermittent basis (other than solely venipuncture for the purposes of obtaining a blood sample), or physical therapy, or speech-language pathology services. Where a patient's sole skilled service need is for skilled oversight of unskilled services (management and evaluation of the care plan as defined in §40.1.2.2), the physician must include a brief narrative describing the clinical justification of this need as part of the certification, or as a signed addendum to the certification;

3. A plan of care has been established and is periodically reviewed by a physician;

4. The services are or were furnished while the patient is or was under the care of a physician;

5. For episodes with starts of care beginning January 1, 2011 and later, in accordance with §30.5.1.1 below, a face-to-face encounter occurred no more than 90 days prior to or within 30 days after the start of the home health care, was related to the primary reason the patient requires home health services, and was performed by an allowed provider type. The certifying physician must also document the date of the encounter.

Example Certification Statement:

I certify that this patient is confined to his/her home and needs intermittent skilled nursing care, physical therapy and/or speech therapy or continues to need occupational therapy. The patient is under my care, and I have authorized services on this plan of care and will periodically review the plan. The patient had a face-to-face encounter with an allowed provider type on 11/01/2016 and the encounter was related to the primary reason for home health care.

Physician's Signature and Date Signed: ***John Doe, MD 11/05/2016***

Physician's Name and Address

John Doe, MD
2121 Washington Pkwy
Suite 220
Washington, DC 20000

Note*: This represents one example of a valid certification statement. Certification statements can be included in varying forms or formats as long as the content requirements (#1-5 above) for the certification are met.*

If the patient is starting home health directly after discharge from an acute/post-acute care setting where the physician, with privileges, that cared for the patient in that setting is certifying the patient's eligibility for the home health benefit, but will not be following the patient after discharge, then the certifying physician must identify the community physician who will be following the patient after discharge. One of the criteria that must be met for a patient to be considered eligible for the home health benefit is that the patient must be under the care of a physician (number 4 listed above). Otherwise, the certification is not valid.

The certification must be complete prior to when an HHA bills Medicare for reimbursement; however, physicians should complete the certification when the plan of care is established, or as soon as possible thereafter. This is longstanding CMS policy as referenced in Pub 100-01, Medicare General Information, Eligibility, and Entitlement Manual, chapter 4, section 30.1. It is not acceptable for HHAs to wait until the end of a 60-day episode of care to obtain a completed certification/recertification.

30.5.1.2 – Supporting Documentation Requirements

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

As of January 1, 2015, documentation in the certifying physician's medical records and/or the acute /post-acute care facility's medical records (if the patient was directly admitted to home health) will be used as the basis upon which patient eligibility for the Medicare home health benefit will be determined. Documentation from the certifying physician's medical records and/or the acute /post-acute care facility's medical records (if the patient was directly admitted to home health) used to support the certification of home health eligibility must be provided, upon request, to the home health agency, review entities, and/or the Centers for Medicare and Medicaid Services (CMS). In turn, an HHA must be able to provide, upon request, the supporting documentation that substantiates the eligibility for the Medicare home health benefit to review entities and/or CMS. If the documentation used as the basis for the certification of eligibility is not sufficient to demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment will not be rendered for home health services provided.

The certifying physician and/or the acute/post-acute care facility medical record (if the patient was directly admitted to home health) for the patient must contain information that justifies the referral for Medicare home health services. This includes documentation that substantiates the patient's:

- Need for the skilled services; and
- Homebound status;

The certifying physician and/or the acute/post-acute care facility medical record (if the patient was directly admitted to home health) for the patient must contain the actual clinical note for the face-to-face encounter visit that demonstrates that the encounter:

- Occurred within the required timeframe,
- Was related to the primary reason the patient requires home health services; and
- Was performed by an allowed provider type.

This information can be found most often in clinical and progress notes and discharge summaries. *While the face-to-face encounter must be related to the primary reason for home health services, the patient's skilled need and homebound status can be substantiated through an examination of all submitted medical record documentation from the certifying physician, acute/post-acute care facility, and/or HHA (see below). The synthesis of progress notes, diagnostic findings, medications, nursing notes, etc., help to create a longitudinal clinical picture of the patient's health status.*

- Information from the HHA, such as the *plan of care required per 42 CFR §409.43 and the* initial and/or comprehensive assessment of the patient required per 42 CFR *§*484.55, can be incorporated into the certifying physician's medical record for the patient and used to support the patient's homebound status and need for skilled care. However, this information must be corroborated by other medical record entries in the certifying physician's and/or the acute/post-acute care facility's medical record for the patient. *This means that the appropriately incorporated HHA information, along with the certifying physician's and/or the acute/post-acute care facility's medical record, creates a clinically consistent picture that the patient is eligible for Medicare home health services.*

- *The certifying physician demonstrates the incorporation of the HHA information into his/her medical record for the patient by signing and dating the material. Once incorporated, the documentation from the HHA, in conjunction with the certifying physician and/or acute/post-acute care facility documentation, must substantiate the patient's eligibility for home health services.*

40.1.2.8 - Wound Care

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

Care of wounds, (including, but not limited to, ulcers, burns, pressure sores, open surgical sites, fistulas, tube sites, and tumor erosion sites) when the skills of a licensed nurse are needed to provide safely and effectively the services necessary to treat the illness or injury, 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, NPWT using conventional DME systems or NPWT using a disposable device.* 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,* administration of prescription medications, etc.) of wounds with the following characteristics, the skills of a licensed nurse are usually reasonable and necessary:

- 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);

- 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.

EXAMPLE 1:

A patient has a second-degree burn with full thickness skin damage on the back. The wound is cleansed, followed by an application of Sulfamylon. While the wound requires skilled monitoring for signs and symptoms of infection or complications, the dressing change requires skilled nursing services. The home health record at each visit must document the need for the skilled nursing services.

EXAMPLE 2:

A patient experiences a decubitus ulcer where the full thickness tissue loss extends through the dermis to involve subcutaneous tissue. The wound involves necrotic tissue with a physician's order to apply a covering of a debriding ointment following vigorous irrigation. The wound is then packed loosely with wet to dry dressings or continuous moist dressing and covered with dry sterile gauze. Skilled nursing care is necessary for proper treatment. The home health record at each visit must document the need for the skilled nursing services.

NOTE: This section relates to the direct, hands on skilled nursing care provided to patients with wounds, including any necessary dressing changes on those wounds. While a wound might not require this skilled nursing care, the wound may still require skilled monitoring for signs and symptoms of infection or complication (see §40.1.2.1) or *for* skilled teaching of wound care to the patient or the patient's family (see §40.1.2.3). *For an example of when wound care is provided separately from the furnishing of NPWT using a disposable device, see §50.4.4.*

50.4 - Medical Supplies (Except for Drugs and Biologicals Other Than Covered Osteoporosis Drugs), the Use of Durable Medical Equipment *and Furnishing Negative Pressure Wound Therapy Using a Disposable Device*

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

50.4.4 - Negative Pressure Wound Therapy Using a Disposable Device

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

Sections 1834 and 1861(m)(5) of the Act require a separate payment to an HHA for an applicable disposable device when furnished on or after January 1, 2017, to an individual who receives home health services for which payment is made under the Medicare home health benefit. Section 1834 of the Act defines an applicable device as a disposable NPWT device that is an integrated system comprised of a non-manual vacuum pump, a receptacle for collecting exudate, and dressings for the purposes of wound therapy used in lieu of a conventional NPWT DME system. As required by §1834 of the Act, the separate payment amount for a disposable NPWT device is to be set equal to the amount of the payment that would be made under the Medicare Hospital Outpatient Prospective Payment System (OPPS) using the Level I HCPCS code, otherwise referred to as Current Procedural Terminology (CPT) codes, for which the description for a professional service includes the furnishing of such a device.

Payment for HH visits related to wound care, but not requiring the furnishing of an entirely new disposable NPWT device, will be covered by the HH PPS episode payment and must be billed using the HH claim. Where a home health visit is exclusively for the purpose of furnishing NPWT using a disposable device, the HHA will submit only a type of claim that will be paid for separately outside the HH PPS (TOB 34x). Where, however, the home health visit includes the provision of other home health services in addition to, and separate from, furnishing NPWT using a disposable device, the HHA will submit both a home health claim and a TOB 34x—the home health claim for other home health services and the TOB 34x for furnishing NPWT using a disposable device.

EXAMPLE:

A patient requires NPWT for the treatment of a wound. On Monday, a nurse assesses a patient's wound, applies a new disposable NPWT device, and provides wound care education to the patient and family. The nurse returns on Thursday for wound assessment and replaces the fluid management system (or dressing) for the existing disposable NPWT, but does not replace the entire device. The nurse returns the following Monday, assesses the patient's condition and the wound, and replaces the device that had been applied on the previous Monday with a new disposable NPWT device. In this scenario, the billing procedures are as follows:

For both Monday visits, all the services provided by the nurse were associated with furnishing NPWT using a disposable device. The nurse did not provide any services that were not associated with furnishing NPWT using a disposable device. Therefore, all the nursing services for both Monday visits should be reported on TOB 34x with CPT code 97607 or 97608. None of the services should be reported on the HH claim.

For the Thursday visit, the nurse checked the wound, but did not apply a new disposable NPWT device, so even though the nurse provided care related to the wound, those services would not be considered furnishing NPWT

using a disposable device. Therefore, the services should be reported on bill type 32x and no services should be reported on bill type 34x.

For instructions on billing for NPWT using a disposable device, see Pub. 100-04, Medicare Claims Processing Manual, chapter 10, Section 90.3 – Billing Instructions for Disposable Negative Pressure Wound Therapy Services.

60.4 - Coinsurance, Copayments, and Deductibles

(Rev. 233, Issued: 02-24-17, Effective: 01-01-17, Implementation: 03-27-17)

There is no coinsurance, copayment, or deductible for home health services and supplies other than the following:

- coinsurance required for durable medical equipment (DME) *and furnishing NPWT using a disposable device* covered as a home health service; and

- deductible and coinsurance for the osteoporosis drug, which is part of the home health benefit only paid under Part B.

The coinsurance liability of the beneficiary for DME and *the* osteoporosis drug furnished as a home health service is 20 percent of the fee schedule amount for the services. *Coinsurance for furnishing NPWT using a disposable device as a home health service is 20 percent of the payment amount.*