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Home Infusion Therapy Services Benefit Beginning January 2021
Frequently Asked Questions

1. *What does the Medicare home infusion therapy services benefit cover?*

The Medicare home infusion therapy services benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment (DME) benefit), remote monitoring, and monitoring services for the provision of home infusion drugs, furnished by a qualified home infusion therapy supplier in the individual's home. The home infusion therapy services are covered for the safe and effective administration of certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is an item of DME. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the DME benefit.

2. *How is the home infusion therapy services benefit separate from DME benefit?*

In order to avoid making duplicative payment, the training and education furnished under the DME benefit is explicitly excluded from the home infusion therapy services payment. The home infusion therapy services benefit provides a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the infusion therapy services furnished in the patient's home by a qualified home infusion therapy supplier. Therefore, the professional services covered under the DME benefit are not covered under the home infusion therapy services benefit. While the two benefits exist in tandem, the services are unique to each benefit and billed and paid for under separate payment systems. The home infusion therapy services benefit is a separate payment in addition to the existing payment for the DME external infusion pump, supplies (including the furnishing of the home infusion drug), and related services covered under the DME benefit.

For more information, please review this special MLN Matters article entitled, "Medicare Part B Home Infusion Therapy Services with the Use of Durable Medical Equipment" - https://www.cms.gov/files/document/se19029.pdf

3. *Who can bill for the home infusion therapy services payment?*

Only a qualified home infusion therapy supplier can bill for services under the new home infusion therapy services benefit. A qualified home infusion therapy supplier must be accredited by a Medicare approved Accreditation Organization (AO) and is required to enroll in Medicare as a Part B supplier (new specialty D6). A home infusion therapy supplier is not required to enroll as a DME supplier, but a DME supplier or Home Health Agency should consider enrolling as a home infusion therapy supplier if they intend to provide home infusion therapy services beyond what is covered under the DME benefit or Home Health benefit, respectively. Section

1861(iii)(3)(D)(i) of the Social Security Act defines a qualified home infusion therapy supplier as a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider of services or supplier furnishes items or services.

4. *Is the qualified home infusion therapy supplier required to furnish the infusion pump and the home infusion drug?*

No, the qualified home infusion therapy supplier is not required to furnish the infusion pump, home infusion drug, or related pharmacy services. The infusion pump, drug, other supplies, and the services required to furnish these items (that is, the compounding and dispensing of the drug) remain covered under the DME benefit. Pharmacy services, remote or otherwise, furnished by a Medicare enrolled DMEPOS supplier, associated with the preparation and dispensing of home infusion drugs are covered under the DME benefit and are not payable under this specific home infusion therapy services benefit.

5. *Who is enrolled in Medicare as a qualified Home Infusion Therapy Supplier?*

Here is the public link to the qualified Home Infusion Therapy Supplier listing including the localities that they serve: https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/home-infusion-therapy-providers

6. *What are the patient eligibility requirements for home infusion therapy services?*

To be eligible to receive home infusion therapy services under the home infusion therapy benefit, a beneficiary must have Medicare Part B and meet each of the following requirements:

A. The beneficiary must be under the care of an applicable provider, as defined in section 1861(iii)(3)(A) of the Act as a physician, nurse practitioner, or physician assistant.
B. The beneficiary must be under a physician-established plan of care that meets the requirements specified in 42 CFR 414.1515 and 42 CFR 486.520, as described in section 320.5 of this chapter.

7. *If a patient is eligible for both the home infusion therapy benefit and the home health benefit, which benefit would cover the home visit?*

If a patient receiving home infusion therapy is also under a home health plan of care and receives a visit that is unrelated to the administration of the home infusion drug, then payment for the home health visit would be covered under the Home Health Prospective Payment System (HH PPS) and billed on the home health claim. Additionally, if a patient is receiving an infusion drug that is not identified as a “home infusion drug”, then the professional services for the administration of the drug would remain covered under the HH PPS if the patient is eligible for home health services.

If the home visit includes the provision of home health services in addition to, and separate from, home infusion therapy services, the home health agency (also enrolled as a qualified home infusion therapy supplier) would submit both a home health claim under the HH PPS and a home infusion therapy services claim under the home infusion therapy services benefit. However, the agency must separate the time spent furnishing services covered under the HH PPS from the time spent furnishing services covered under the home infusion therapy services benefit.

When the home health agency (HHA) furnishing home health services is also enrolled as a qualified home infusion therapy supplier, and a home visit is exclusively for the purpose of the administration of the home infusion drug, the home health agency would only submit a home infusion therapy services claim under the home infusion therapy services benefit.

8. *If a HHA does not intend to become a qualified home infusion therapy supplier or bill Medicare Part B for these home infusion therapy services, can the infusion services still be provided by the HHA, but not bill Medicare for the additional payment they could have collected under the home infusion therapy service benefit?*

For dates of service on our after January 1, 2021, home infusion therapy services will be excluded from coverage under the Medicare Home Health benefit as required by the 21st Century Cures Act. Any Medicare provider (e.g. HHA) is not allowed to provide a mix of covered and non-covered services to a Medicare beneficiary, especially when another provider (e.g. a qualified home infusion therapy supplier) is able and available to provide the service covered under the new benefit. If the HHA does not intend to enroll as a qualified home infusion therapy supplier, they must notify the beneficiary that the home infusion therapy service is no longer covered under their home health benefit and offer the beneficiary the option to receive the necessary professional care from a qualified home infusion therapy supplier for dates of service on or after January 1, 2021.

9. *If an HHA is currently caring for a patient that qualifies for the home health benefit and that same patient is receiving home infusion services that would qualify under the home infusion therapy benefit and included in the patient's current plan of care, will the HHA be required to find a home infusion therapy supplier to provide the infusion services for those patients who are receiving home health services?*

If the HHA does not intend to enroll as a qualified home infusion therapy supplier, they must notify the beneficiary that the home infusion therapy service is no longer covered under their home health benefit and offer the beneficiary the option to receive the necessary professional care from a qualified home infusion therapy supplier for dates of service on or after January 1, 2021.

10. *What are the home infusion therapy plan of care requirements?*

A. Plan of Care Content - The plan of care must prescribe the type, amount, and duration of the home infusion therapy services (including monitoring) that are to be furnished. The plan of care would also include the specific medication, the prescribed dosage and frequency as well as the professional services to be utilized for treatment.
B. Physician's Orders - The physician's orders for services in the plan of care must specify at what frequency the services will be furnished, as well as the discipline that will furnish the ordered professional services. Orders for care may indicate a specific range in frequency of visits to ensure that the most appropriate level of services is furnished. The plan of care would specify the care and services necessary to meet the patient specific needs
C. Physician's Signature - The plan of care must be signed and dated by the ordering physician prior to submitting a claim for payment. The ordering physician must sign and date the plan of care upon any changes to the plan of care.
D. Periodic Review - The plan of care for each patient must be periodically reviewed by the physician. The expectation is that the physician is active in the patient's care and can make appropriate decisions related to the course of therapy if changes are necessary in regards to the progress and goals of the patient's infusion therapy.

11. What is the physician establishing the plan of care required to do?

The physician establishing the plan of care is required to consult with the DME supplier and the home infusion therapy supplier. In order to ensure that home infusion therapy is safe and effective and stays current throughout the course of treatment, the physician who orders the home infusion therapy services must review the plan of care on a regular basis in coordination with the DME supplier and the home infusion therapy supplier. The plan of care must be signed and dated by the ordering physician prior to submitting a claim for payment. The ordering physician must sign and date the plan of care upon any changes to the plan of care.

12. What services must the qualified home infusion therapy supplier furnish on a 7-day-a-week, 24 hour-a-day basis?

The qualified home infusion therapy supplier must furnish home infusion therapy services to individuals with acute or chronic conditions requiring administration of home infusion drugs; and ensure the safe and effective provision and administration of home infusion therapy services on a 7- day-a-week, 24-hour a-day basis.

Specifically:

A. Professional services, including nursing services.
B. Patient training and education not otherwise paid for as durable medical equipment as described in 42 CFR 424.57(c)(12).
C. Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.
D. All home infusion therapy suppliers must provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all

applicable state and federal laws and regulations. This could include the applicable provisions in the Federal Food, Drug, and Cosmetic Act.

13. Are qualified home infusion suppliers required to provide training and education?

Yes, consistent with section 1861(iii)(2)(B) of the Act, qualified home infusion suppliers are required to provide patient training and education, not otherwise paid for as durable medical equipment, and as described in 42 CFR 424.57(c)(12). In addition, the patient training and education requirements are consistent with standards that are already in place, as established by the current accrediting organizations of home infusion therapy suppliers. The DME supplier standards require a DME supplier to provide beneficiaries with the necessary education and instruction on how to use Medicare-covered items safely and effectively. Therefore, the professional services under the home infusion therapy services benefit would include the teaching and training on the provision of home infusion drugs that is not already required under the DME benefit. This education may include education related to vascular access device maintenance, medication education and disease management, medication storage and patient safety, and self-monitoring.

14. How is remote monitoring performed?

Remote monitoring may be performed through telephone or other electronic communication, based on the plan of care and the patient's preference of communication. Remote monitoring may include the use of a telecommunications system through which patients are monitored by electronic submission of self-obtained vital signs, such as weight, blood pressure, and heart rate. The patient must be instructed on obtaining vital signs and on self-monitoring equipment use. An off-site monitoring service may also be utilized to communicate any abnormal results to the clinician for adjustments to the plan of care as needed. A qualified home infusion therapy supplier may not bill separately for any services furnished via remote monitoring. This service is considered bundled into the payment made for an infusion drug administration calendar day.

15. What drugs and biologicals are considered "home infusion drugs"?

"Home infusion drugs" are defined as parenteral drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of DME covered under the Medicare Part B DME benefit, pursuant to the regulatory definition set out at 42 CFR 486 Subpart I and the statutory definition set out in section 1861(iii)(3)(C) of the Act, and incorporated by cross reference at section 1834(u)(7)(A)(iii) of the Act. Section 1861(iii)(3)(C) of the Act also states that such term "home infusion drugs" does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list. This means that Medicare payment for home infusion therapy services is for services furnished in coordination with the furnishing of the intravenous and subcutaneous infusion drugs and biologicals specified on the DME LCD for External Infusion Pumps (L33794), with the exception of insulin pump

systems and drugs and biologicals on a self-administered drug exclusion list. In order for the drugs and biologicals to be covered under the Part B DME benefit they must require infusion through an external infusion pump and be necessary for the treatment of an illness or injury.

16. What are the home infusion therapy drugs beginning January 2021?

For a list of drugs that would qualify for the home infusion therapy services, please see Section 411.3, entitled "Home Infusion Drugs: Healthcare Common Procedural Coding System (HCPCS) Drug Codes", found within the Medicare Claims Processing Manual Publication 100-04, Chapter 32.

Also see the MLN Matters Article: Update to 'J' Drug Code List for Billing Home Infusion Therapy (HIT) Services.

17. What if a new home infusion therapy drug does not yet have a unique J-code?

Beginning January 1, 2021, your MAC may determine the payment category for any new home infusion drug additions to the DME LCD for External Infusion Pumps (L33794) as identified by the following Not-Otherwise-Classified (NOC) codes:

- J7799 - Not otherwise classified drugs, other than inhalation drugs, administered through DME
- J7999 - Compounded drug, not otherwise classified.

When either one of these NOC codes is used for a home infusion drug, the home infusion therapy supplier must identify the name of the drug in the comment section (data element 2400/SV101-7 of the 837P or Item 19 of the CMS-1500) of the professional service claim for the corresponding home infusion therapy service G-code.

18. Does Medicare cover home infusion for other drugs that do not meet the definition of "home infusion therapy drugs"?

The professional services related to the home administration of other infusion drugs (e.g. antibiotics) are not covered under the Part B home infusion therapy benefit. However, depending on clinical reasonableness, other drugs may be covered under Part D; and related professional services at home may be covered under the Part A home health benefit if the patient meets certain eligibility criteria (e.g. is certified as homebound by a doctor), or under a Medicare Advantage plan.

19. What does a unit of single payment mean?

A unit of single payment is a bundled payment and is made for items and services furnished by a qualified home infusion therapy supplier per payment category for each infusion drug administration calendar day. The single payment amount represents payment in full for all costs associated with the furnishing of home infusion therapy services. Any home infusion therapy services furnished outside of an infusion drug administration calendar day is considered bundled into the payment for the infusion drug administration calendar day.

20. What is an "Infusion Drug Administration Calendar Day"?

An "infusion drug administration calendar day" is the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex

that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.

21. When is payment for an "infusion drug administration calendar day" made?

Payment for an "infusion drug administration calendar day" is only made if a beneficiary is furnished certain drugs and biologicals administered through an item of covered DME, and payable only to suppliers accredited and enrolled in Medicare as a "qualified home infusion therapy supplier." The beneficiary must be under the care of an applicable provider, defined as a physician, nurse practitioner, or physician's assistant, and must be under the care of a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services. Payment is made only on those days in which the home infusion therapy supplier is in the beneficiary's home furnishing home infusion therapy services.

22. W*hat are the three payment categories for home infusion drugs?*

Payment category 1 includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, such as antifungals and antivirals, inotropic and pulmonary hypertension drugs, pain management drugs, chelation drugs; but excludes chemotherapy and other highly complex drugs or biologicals.

Payment category 2 includes subcutaneous infusions for therapy or prophylaxis, such as certain subcutaneous immunotherapy infusions.

Payment category 3 includes intravenous infusions, including certain chemotherapy drugs, and other highly complex drugs and biologicals.

23. What are the billing codes and payment categories for home infusion therapy professional services (G-Codes)?

G0068: Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes Short Descriptor: Adm IV infusion drug in home

G0069: Professional services for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes Short Descriptor: Adm SQ infusion drug in home

G0070: Professional services for the administration of intravenous chemotherapy or other intravenous highly complex drug or biological infusion for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm of IV chemo drug in home

G0088: Professional services, initial visit, for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or

biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm IV drug 1st home visit

G0089: Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm SubQ drug 1st home visit

G0090: Professional services, initial visit, for the administration of intravenous chemotherapy or other highly complex infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes. Short Descriptor: Adm IV chemo 1st home visit

For more information, please see this MLN Matters article entitled "Billing for Home Infusion Therapy Services on or After January 1, 2021" - https://www.cms.gov/files/document/mm11880.pdf

24. What is the difference between "initial visit" and "subsequent visit"?

To differentiate the initial visit from all subsequent visits, home infusion therapy suppliers may only bill for an initial visit for a new patient or a patient who had previously received their last home infusion therapy service visit more than 60 days prior to the next initial home infusion therapy service visit. If any one of the home infusion therapy G-codes is found in the beneficiary's claims history within 60-days prior to the date of service for an initial visit, then the initial visit claim will be rejected. For more information, please see this MLN Matters article entitled "Billing for Home Infusion Therapy Services on or After January 1, 2021" - https://www.cms.gov/files/document/mm11880.pdf

25. Is the payment amount of each G-code based on multiple units of 15-minute increments?

No. The payment amount of each G-code is based on only one single unit of payment per drug category for each infusion drug administration calendar day. While the qualified HIT supplier should submit claims for the appropriate G-code in multiple units of 15-minute increments to report the actual duration of each HIT service visit, the payment will be equal to only one single unit per visit. The payment amounts per unit are equal to 5 hours of infusion therapy in a physician's office. For more information, please see the MLN Matters article entitled "Billing for Home Infusion Therapy Services on or After January 1, 2021" - https://www.cms.gov/files/document/mm11880.pdf

26. Does the Home Infusion Therapy service benefit beginning January 2021 apply to Medicare Advantage Plans or is it just available for traditional Medicare patients?

Medicare Advantage Plans are required to include all Medicare Part B benefits. The home infusion therapy service is a Part B benefit. This new benefit itself does not cover drugs, but rather the professional (including nursing) services associated with administering certain drugs in the patient's home. The home infusion drugs eligible for coverage of home infusion therapy services must be infused via an external infusion pump covered under the DME benefit and are thereby paid under the DME benefit (which is under Medicare Part B). Many Medicare Advantage Plans also include Part D and may offer other services not covered under original Medicare. For additional questions regarding coverage and payment for home infusion therapy services, please contact your Medicare Advantage Plan directly.