



Medicare Part B Home Infusion Therapy Services With The Use of Durable Medical Equipment

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PROVIDER TYPES AFFECTED

This special MLN Matters® Article is intended for entities seeking accreditation to become qualified suppliers that furnish home infusion therapy (HIT) services in coordination with the furnishing of home infusion drugs administered through an item of durable medical equipment (DME) beginning in calendar year 2021 and in subsequent years.

BACKGROUND

Section 1834(u)(1) of the Social Security Act (the Act), as added by Section 5012 of the 21st Century Cures Act (Pub. L. 144-255), established a new Medicare HIT benefit under Medicare Part B. The Medicare HIT benefit is for coverage of HIT services for 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 a DME item. This benefit is effective January 1, 2021.

For more information regarding services furnished in calendar years 2019 and 2020, review the Home Infusion Therapy Temporary Transitional Payment Frequently Asked Questions (FAQ) at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf>.

Section 1861(iii)(3)(D)(i) of the Act defines a qualified HIT 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 and that—

(I) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

(II) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

(III) Is accredited by an organization designated by the Secretary pursuant to section 1834(u)(5); and

(IV) Meets such other requirements as the Secretary determines appropriate.

A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements listed above.

WHAT YOU NEED TO KNOW

HIT involves the parenteral administration of drugs or biologicals to an individual at home, outside of the hospital or clinic setting. There are a variety of items and services involved in home infusion in order to ensure that therapy is safe and effective in the home. In general, as shown in Figure 1, HIT consists of four components:

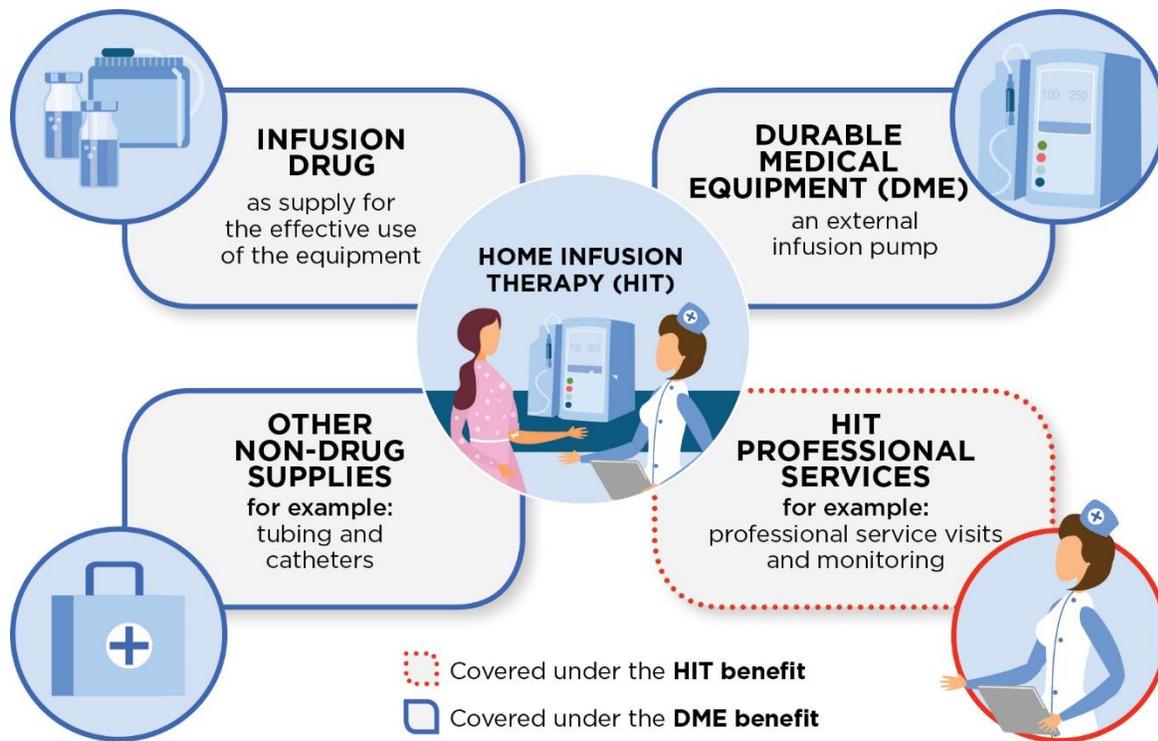
- (1) The infusion drug (covered under the DME benefit as a supply necessary for the effective use of an infusion pump covered under the DME benefit),
- (2) The external infusion pump and related equipment (for example, an IV pole),
- (3) Supplies other than the drug (for example, tubing and catheters), and
- (4) Professional services, such as nurse visits.

Medicare ensures coverage of these components through a combination of benefit categories:

The **DME benefit** covers three components: the external infusion pump, the related supplies, and the infusion drug. Additionally, this benefit covers the related services required to furnish these items (e.g., pharmacy services, delivery, equipment set up, maintenance of rented equipment, and training and education on the use of the covered items) by an eligible DME supplier. No payment is made under the HIT benefit for these DME items and services.

The new **HIT benefit** covers the service component, meaning the professional services, training and education (not otherwise covered under the DME benefit), and monitoring furnished by a qualified HIT supplier needed to administer the home infusion drug in the patient's home.

Figure 1: HIT Components



It is important to note that certain drugs are only covered under Part B of the Medicare program, either incident to a physician’s professional service, as a DME supply, or in specific cases, such as immunosuppressive drugs, oral anti-cancer drugs, oral anti-emetic drugs, erythropoietin for dialysis patients, and intravenous immune globulin. Drugs administered through infusion pumps are covered with the pump under the DME benefit as supplies necessary for the effective use of the DME (infusion pump) and listed on the DME LCD for External Infusion Pumps¹.

To be eligible for coverage under the DME benefit, the pump and drug must be appropriate for use by the patient and/or caregiver in the patient’s home and it must be medically necessary to use the pump to administer the drug. To be eligible for coverage of services under the HIT benefit, an individual must be receiving an intravenous or subcutaneous drug or biological included on the DME LCD for External Infusion Pumps, with the exception of insulin pump systems and any drugs included on a self-administered drug (SAD) exclusion list.

Section 1834(u)(1)(A)(ii) of the Act states that payment is for an “infusion drug administration calendar day” in the individual’s home, and refers to payment only for the date on which professional services were furnished to administer such drugs to such individual. In the CY 2019 Medicare Home Health Prospective Payment System final rule (83 FR 56583), CMS stated in regulation that payment for an “infusion drug administration calendar day,” is for the day on

¹ <https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD+and+PA>

which home infusion therapy services are furnished by skilled professionals in the individual's home on a 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 (42 CFR 486.505). The payment amount for an "infusion drug administration calendar day" covers the cost of services furnished in coordination with the administration of home infusion drugs in the patient's home. These services include: professional services, including nursing; training and education (not otherwise paid for under the Medicare Part B DME benefit); and monitoring and remote monitoring services.

Qualified HIT suppliers can only bill and be paid for the HIT services furnished on the day on which a professional is physically present in the patient's home and an infusion drug is being administered on such day. Medicare payment for an infusion drug administration calendar day is separate from the payment for DME items and services, therefore, a supplier could still be paid for DME items and services under the DME benefit, even if the supplier does not receive payment for home infusion therapy services under the HIT benefit. The HIT single payment amount does not include payment for the DME external infusion pump, supplies (including the home infusion drug), and related services paid under the DME benefit. The HIT single payment is instead intended to cover the monitoring and other professional services that occur in the patient's home (and that are not for the set-up and training on the routine use of the external infusion pump). The external infusion pump, supplies, and the infusion drug continue to be covered in accordance with DME policies regardless of when and how often a skilled professional is in the individual's home to provide home infusion therapy services.

HOME INFUSION ITEMS AND SERVICES FURNISHED UNDER THE DME BENEFIT

Under the DME benefit, suppliers bill for external infusion pumps covered as DME and supplies (for example, intravenous catheter supplies and infusion drugs). DME payment for these items includes the related services required to furnish these items (for example, intake and assessment, delivery and set-up, training, pharmacy services, and follow-up). Under this benefit, the supplier is required to consult with the prescribing physician, as needed, to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment, item(s), and/or service(s). This includes reviewing the beneficiary's record as appropriate and incorporating any pertinent information related to the beneficiary's condition(s) which affect the provision of the DME and related services, or to the actual equipment, item(s) and service(s) provided, in collaboration with the prescribing physician; and maintaining the prescription, any certificates of medical necessity (CMNs), and pertinent documentation from the beneficiary's prescribing physician in the beneficiary's record²

The DME supplier is also responsible for delivery and set up of the equipment, as well as training and education on operation of the infusion pump. According to the DMEPOS Quality

² <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DMEPOS-Quality-Standards-Eff-01-09-2018.pdf>

Standards, supplier responsibilities include: providing relevant and appropriate information related to the set-up, routine use, cleaning, troubleshooting, infection control practices, and maintenance of the equipment and supplies; documenting in the patient's record that the patient and/or caregiver has received training and written instructions on the use of equipment and supplies; and ensuring the patient and/or caregiver can use all equipment and supplies safely and effectively³.

The DME benefit also covers pharmacy services (i.e., drug preparation and dispensing), including sterile compounding, that are associated with the furnishing of the home infusion drug. Section 1861(iii)(3)(C) defines a home infusion drug as a parenteral drug or biological 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, but does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list. External infusion pumps are covered under the DME benefit, and drugs used in conjunction with a covered pump are considered supply items for the pump and eligible for reimbursement on that basis. Specifically, in accordance with the DMEPOS Supplier Standards, a supplier that furnishes a drug used as a Medicare-covered supply with durable medical equipment or prosthetic devices must be licensed by the State to dispense drugs⁴.

In general, the Medicare allowed payment amount for an item or service is payment for furnishing that item or service and includes payment for everything involved in, and necessary for furnishing that item or service. For example, supply code A4222 includes the cassette or bag, diluting solutions, tubing and other administration supplies, port cap changes, as well as compounding charges and preparation charges.

HOME INFUSION THERAPY SERVICES FURNISHED UNDER THE HIT BENEFIT

The HIT benefit is intended to be a separate payment from the amount paid under the DME benefit, explicitly covering the professional services that occur in the patient's home (and that are not for the set-up and training on the routine use of the external infusion pump), as well as monitoring and remote monitoring services for the provision of 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*. The HIT benefit covers services distinct from those under the DME benefit (as discussed above) and could conceivably include, for example:

- Training and education on care and maintenance of vascular access devices:
 - Hygiene education

³ *ibid*

⁴ <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DMEPOSSupplierStandards.pdf>

- Instruction on what to do in the event of a dislodgement or occlusion
- Education on signs and symptoms of infection
- Teaching and training on flushing and locking the catheter
- Dressing changes and site care
- Patient assessment and evaluation:
 - Review history and assess current physical and mental status, including obtaining vital signs
 - Assess any adverse effects or infusion complications
 - Evaluate family and caregiver support
 - Review prescribed treatment and any concurrent oral and/or over-the-counter treatments
 - Obtain blood for lab-work
- Medication and disease management education:
 - Instruction on self-monitoring
 - Education on lifestyle and nutritional modifications
 - Education regarding drug mechanism of action, side effects, interactions with other medications, adverse and infusion-related reactions
 - Education regarding therapy goals and progress
 - Instruction on administering pre-medications and inspection of medication prior to use
 - Education regarding household and contact precautions and/or spills
- Monitoring/remote monitoring services:
 - Communicate with patient and physician regarding changes in condition and treatment plan
 - Monitor patient response to therapy
 - Assess compliance

Qualified HIT suppliers can only bill for HIT for days on which a professional is physically present in the patient's home and an infusion drug is being administered. This means that, although remote monitoring is covered under the HIT benefit, the supplier can only bill for services that are furnished when a skilled professional is in the patient's home on an "infusion drug administration calendar day." Any services furnished that do not occur on an "infusion drug

administration calendar day” are built into the single payment for the days on which the skilled professional is in the patient’s home and the drug is being infused.

Table 1: Benefit Categories and Codes for Home Infusion Therapy Services

Benefit	Item / Service	Codes
Durable Medical Equipment (DME)	Home Infusion Drug External Infusion Pump Medical Supplies	J-codes ⁵ E0779, E0781, E0791, E0780, K0455 A4221, A4222, K0552, A4602, K0604, K0605
Home Infusion Therapy (HIT)	In-Home Professional Services: Training and Education (not included under DME benefit); and Professional Services, Including Nursing Care (e.g., dressing changes and site care) Monitoring and Remote Monitoring Services (bundled into the payment amount for the professional services visit)	G0068 (for other intravenous drugs), G0069 (for subcutaneous drugs), G0070 (for chemotherapy drugs)

ACCREDITATION FOR HOME INFUSION THERAPY

A qualified home infusion supplier must be accredited by a CMS approved accreditation organization prior to providing services under the HIT benefit. To locate or inquire about an approved accreditation organization, you may submit a question to the CMS HIT Accreditation mailbox at HITaccreditation@cms.hhs.gov.

⁵ A list of qualified J-codes is found in the HIT Temporary Transitional Payment Frequently FAQ document at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Home-Infusion-Therapy/Downloads/Home-Infusion-Therapy-Services-Temp-Transitional-Payment-FAQs.pdf>. Please note that J2274, J2278, J1559, and J9200 are not covered under the HIT benefit beginning CY 2021.

ADDITIONAL INFORMATION

If you have questions, your MACs may have more information. Find their website at <http://go.cms.gov/MAC-website-list>.

DOCUMENT HISTORY

Date of Change	Description
December 13, 2019	We revised this article to correct footnote 5 on page 7 which should have stated J code, J1559, instead of J1159. The article release date was also changed. All other information is unchanged.
December 9, 2019	Initial article released.

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