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THERE IS A NEW HOME INFUSION THERAPY BENEFIT – NOW WHAT?

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INTRODUCTION

INTRODUCTION

- Topics Covered

- History of the 21st Century Cures Act and the progression to the new Home Infusion Therapy (“HIT”) Benefit Program.
- Who is covered under the HIT benefit.
- How to become an accredited and enrolled supplier or provider of the HIT benefit.
- What services are covered under the HIT benefit.
- How providers bill for their services under the HIT benefit.



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BRIEF HISTORY OF 21ST CENTURY CURES ACT & THE NEW HOME INFUSION THERAPY BENEFIT PROGRAM

BRIEF HISTORY OF 21ST CENTURY CURES ACT & THE NEW HIT BENEFIT PROGRAM

- The 21st Century Cures Act (“Cures Act”) was signed into law on December 13, 2016.
- Section 5012 established a new Medicare HIT benefit which went into effect on January 1, 2021.
- The intent and purpose of the new benefit was to cover all professional services provided and coordinated by infusion pharmacies, including the nursing services, that are required to provide home infusions.

21ST CENTURY CURES ACT

- Section 5012 created a separate Medicare Part B benefit category under Section 1861(s)(2)(GG) of the Cures Act for coverage of HIT services needed for the safe and effective administration of home infusion drugs.
- Home infusion drugs are defined as a drug or biological administered intravenously or subcutaneously through a pump that is an item of Durable Medical Equipment (“DME”), for an administration period of 15 minutes or more, in the home of an individual.
- Infusion pump and supplies (including home infusion drugs) will continue to be covered under the Part B DME Benefit.



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DME BENEFIT FOR HOME INFUSION THERAPY

DME BENEFIT

- There are 3 components covered under the DME benefit:
 - The external infusion pump;
 - The related supplies; and
 - The infusion drug.
- The related services required to furnish these items (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.

ELIGIBILITY FOR DME BENEFIT

- In order 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.



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HOME INFUSION THERAPY BENEFIT

WHAT IS HIT?

- HIT allows for the delivery of certain drugs such as anti-infectives, chemotherapy, or treatment for immune deficiencies with the use of a DME pump at a patient's home.
- Different components are needed for proper HIT including:
 - 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);
 - The external infusion pump and related equipment (an IV pole for example);
 - Supplies other than the drug (tubing and catheters); and
 - Professional services such as nurse visits.

HIT BENEFIT

- The new HIT benefit covers the service component which includes:
 - 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.

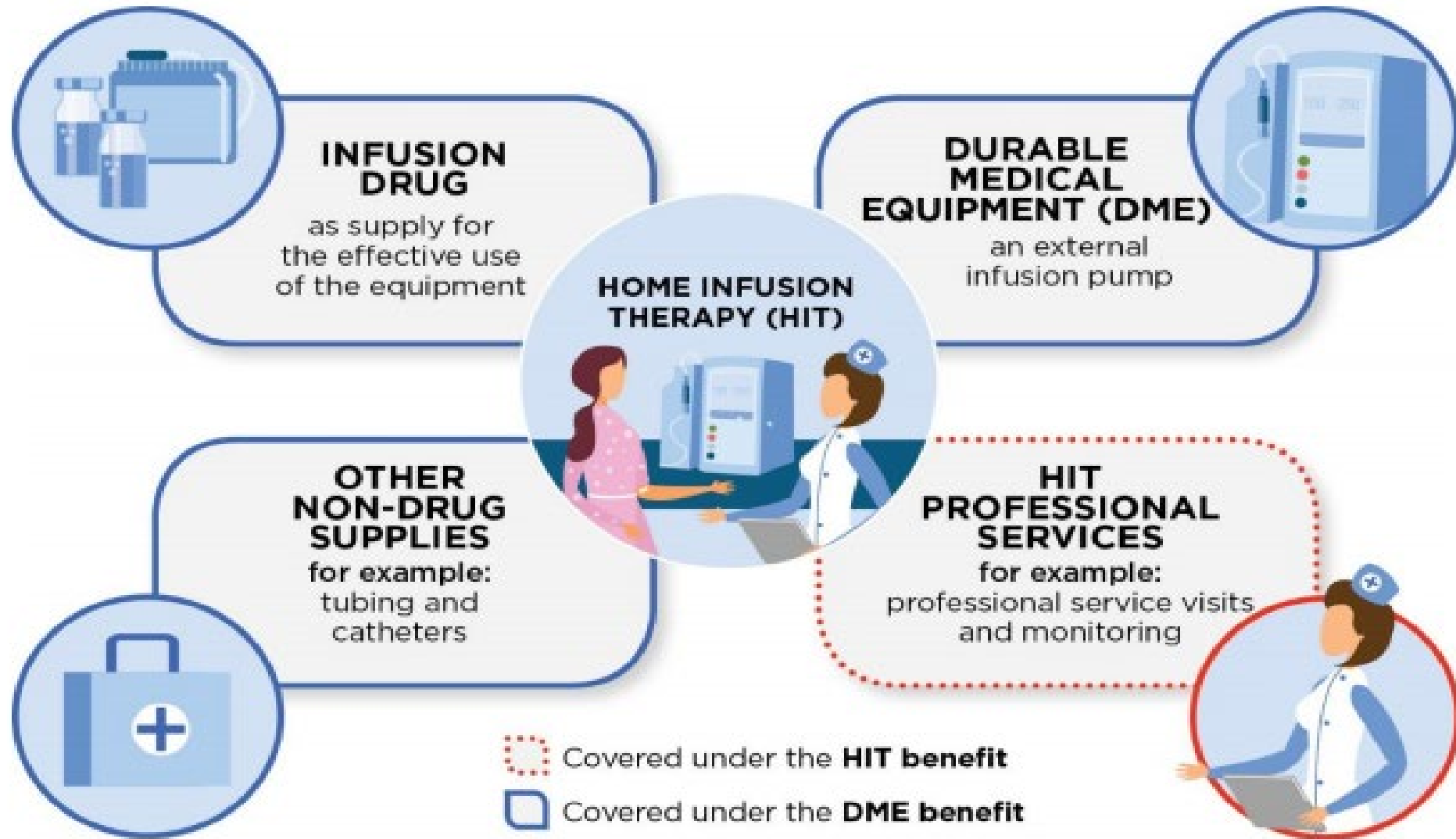
GENERAL OVERVIEW OF HIT BENEFIT

- It is important to note that the DME benefit will continue to cover:
 - The infusion drug;
 - The DME; and
 - Other non-drug supplies.
- The HIT benefit will only cover the professional services needed for the same and effective administration of HIT.
- Provider Types Affected:
 - Entities already accredited or entities seeking accreditation to become qualified suppliers that furnish HIT services in coordination with the furnishing of home infusion drugs administered through an item of DME beginning in calendar year 2021 and in subsequent years.

GENERAL OVERVIEW OF HIT BENEFIT

- Infusion drugs can be administered in multiple health care settings (e.g., inpatient hospitals, skilled nursing facilities, hospital outpatient departments, physicians' offices, and at home).
- Generally, infusion drugs, equipment, supplies, and administration are all covered by Medicare in the inpatient hospital, skilled nursing facility, hospital outpatient departments, and physicians' offices.
- Drugs, equipment, supplies, and services are bundled into a single payment under Medicare Part A.
- Medicare fee-for-service covers outpatient infusion drugs under Medicare Part B, "incident to" a physician's service, provided the drugs are not self-administered.

Figure 1: HIT Components



Source: MLN Matters Number: SE19029 <https://www.cms.gov/files/document/se19029.pdf>

QUALIFIED HIT SUPPLIER

- A qualified HIT supplier is defined as a pharmacy, physician, or other provider of services, or a supplier, licensed by the state in which the supplies or services are furnished.
- A qualified provider or supplier must:
 - furnish infusion therapy to individuals with acute or chronic conditions requiring the administration of home infusion drugs;
 - ensure the safe and effective provision and administration of HIT on a 7-day-a-week, 24-hour-a-day basis;
 - be accredited by an organization designated by the Secretary; and
 - meet other such requirements as the Secretary deems appropriate.
- Supplier may subcontract with a pharmacy, physician, other qualified supplier, or provider of medical services in order to meet these requirements.



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HOME INFUSION THERAPY COVERAGE

WHO IS ELIGIBLE FOR THE BENEFIT?

- To be eligible, a patient must:
 - Be under the care of an applicable provider (physician, nurse practitioner, or physician's assistant); and
 - Be under a physician-established plan of care that prescribes the type, amount, and duration of infusion therapy services to be furnished; and
 - Be receiving an intravenous or subcutaneous drug or biological included on the DME local coverage determination for External Infusion Pumps, except for insulin pump systems and any drugs included on a self-administered drug ("SAD") exclusion list.

PLAN OF CARE REQUIREMENTS

- The plan of care must have physician's orders for services that:
 - Specify what frequency the services will be furnished; and
 - Specify the discipline that will furnish the ordered professional services; and
 - Be signed and dated by the ordering physician prior to submitting a claim for payment.



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HOME INFUSION THERAPY PAYMENTS

PAYMENT FOR QUALIFIED HIT SUPPLIERS

- Payment for HIT services can only be made:
 - if a beneficiary is administered certain drugs and biologicals through an item of covered DME; and
 - to suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies.
- Medicare Part B covers a limited number of home infusion drugs through the DME benefit if:
 - The drug is necessary for the effective use of an external infusion pump classified as DME;
 - The pump must be appropriate for use in the home; and
 - The drug being used is reasonable and necessary for the treatment of an illness or injury.

PAYMENT FOR QUALIFIED HIT SUPPLIERS

- 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.
- A supplier could still be paid for DME items and services under the DME benefit even if the supplier does not receive payment for HIT services under the HIT benefit.

PAYMENT FOR QUALIFIED HIT SUPPLIERS

- Beginning on January 1, 2021, a single payment will now be made to a qualified HIT supplier for the items and services, including:
 - Nursing services;
 - Training and Education;
 - Remote Monitoring; and
 - Other monitoring services needed for safe administration of the home infusion drug.



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DURABLE MEDICAL EQUIPMENT COVERAGE

PAYMENT UNDER DME BENEFIT

- Under the DME benefit, suppliers must consult with the prescribing physician, as needed, to confirm the order and recommend any necessary changes.
- Suppliers will bill for external infusion pumps covered under the DME benefit and supplies including:
 - Intake and assessment;
 - Delivery and set-up;
 - Training;
 - Pharmacy services; and
 - Follow-up.

DUTIES OF DME SUPPLIER

- Responsibilities include:
 - Providing relevant and appropriate information related to 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;
 - Ensuring the patient and/or caregiver can use all equipment and supplies safely and effectively; and
 - Delivery and set up of the equipment.

CATEGORIES FOR PAYMENT OF HOME INFUSION DRUGS

- Home infusion drugs are assigned to 3 payment categories:
 - Category 1
 - Includes certain intravenous antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, and chelation drugs.
 - Category 2
 - Includes subcutaneous immunotherapy and other certain subcutaneous infusion drugs.
 - Category 3
 - Includes certain chemotherapy drugs.

HIT BENEFIT PAYMENTS ARE SEPARATE

- The HIT benefit is intended to be a separate payment from the amount paid under the DME benefit.
- Professional services covered under the DME benefit are not covered under the HIT services benefit.

TRAINING & EDUCATION UNDER HIT BENEFIT

- Training and education on care and maintenance are covered by the HIT benefit which includes:
 - Hygiene education;
 - 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; and
 - Training for dressing changes and site care.

PATIENT ASSESSMENT & EVALUATION UNDER THE HIT BENEFIT

- Patient assessment and evaluation are covered under the HIT benefit and includes:
 - 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; and
 - Obtain blood for lab work.

MEDICATION & DISEASE MANAGEMENT EDUCATION

- Medication and disease management education is covered under the HIT benefit and includes:
 - Instruction on self-monitoring;
 - Education on lifestyle and nutritional modifications;
 - Education regarding drug mechanism of action, side effects, interactions with other medications, and adverse and infusion-related reactions;
 - Education regarding therapy goals and progress;
 - Instruction on administering pre-medications and inspection of medication prior to use; and
 - Education regarding household and contact precautions and/or spills.

MONITORING/REMOTE MONITORING SERVICES

- Although remote monitoring is covered under the HIT benefit, qualified HIT suppliers can only bill for services furnished when a skilled professional is in the patient's home on an infusion drug administration calendar day.
- Monitoring/remote monitoring services is covered under the HIT benefit and includes:
 - Communications with patient and physician regarding changes in condition and treatment plan;
 - Monitoring patient response to therapy; and
 - Assessing compliance.



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HOME INFUSION THERAPY REIMBURSEMENT

WHAT QUALIFIES AS REIMBURSEMENT

- Only therapies that are covered under the external infusion pump (HCPCS code L33794) local coverage determination listed under each region's DME MACS website can be billed.
- Only visits in which nurses are physically on-site on the day that an applicable drug is administered and within 30 days of the drug being dispensed can be billed for reimbursement.
- Patients being provided services by an HHA under a 60-day home health care episode can have separate HIT nursing services billed to Medicare within that time period.

HOW TO BILL

- During the transitional period, HIT pharmacies filed claims for HIT nursing services through one of 4 DME MACs.
- Now, all qualified HIT suppliers, including HHAs and pharmacies, will need to file claims to one of 12 Medicare Part A/Part B MACs instead.
- Professional services for qualifying HIT visits are billed using one of 6 G-codes which determine the amount of reimbursement.

G-CODES

	Category 1	Category 2	Category 3
Description	Intravenous anti-infective, pain management, chelation, pulmonary hypertension, inotropic, and other certain intravenous infusion drugs	Subcutaneous immunotherapy and other certain Subcutaneous infusion drugs	Chemotherapy and other certain highly complex intravenous drugs
G-Code			
Initial Visit	G0088	G0089	G0090
Subsequent Visit	G0068	G0069	G0070

UNITS FOR LENGTH OF TIME

- Along with the G-Code, a length of time will also need to be provided by using numbered units.
- Each numbered unit corresponds to a different length of time.
- The unit number is determined by the amount of time a nurse has spent on-site with patient for the administration of HIT drugs.

Unit	Time
1	<23 minutes
2	= 23 minutes to <38 minutes
3	= 38 minutes to <53 minutes
4	= 53 minutes to <68 minutes
5	= 68 minutes to <83 minutes
6	= 83 minutes to <98 minutes
7	= 98 minutes to <113 minutes
8	= 113 minutes to <128 minutes
9	= 128 minutes to <143 minutes
10	= 143 minutes to <158 minutes

J-CODES

- A proper J-Code must be submitted along with the unit number for the bill to be processed correctly.
- Each J-Code indicates exactly which drug was administered during a HIT session.
- If a J-code is not found in the patient's record when your G-Code is submitted, the claim will be recycled and brought up again after 5 days.
- This process is done a total of 3 times.
- If no match is found after 3 cycles, the claim will be denied.

J-Code	Description
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, Treprostinil, 1 mg

EXAMPLE: BENEFIT CATEGORIES & CODES FOR HIT 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)



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ENROLLMENT AS A HIT SUPPLIER

HOW TO ENROLL

- To enroll in the Medicare program as a HIT supplier, the supplier must meet all of the following requirements:
 - Complete and submit Form CMS-855B (the “Form”) application to its applicable Medicare contractor.
 - Certify via the Form that the HIT supplier meets and will continue to meet the specific requirements and standards.
 - Comply with application fee requirements.
 - Be currently and validly accredited as a HIT supplier by a CMS recognized HIT supplier accreditation organization.
 - Comply With § 414.1515 and all provisions of part 486, Subpart I.
 - Successfully complete the limited categorical risk level of screening under § 424.518.

APPLICATION FEE REQUIREMENTS

- The application fee must be in the amount calculated by CMS in effect for the year during which the application for enrollment is being submitted.
- The application fee will be adjusted by the percentage change in the consumer price index for all urban consumers for the 12-month period ending with June of the previous year.

DENIAL OF ENROLLMENT

- CMS may deny a supplier's enrollment application on any of the following grounds:
 - The supplier does not meet all of the requirements for enrollment or
 - Any of the applicable denial reasons in § 424.530.



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QUESTIONS?

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THANK YOU

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