



Home Infusion Therapy Supplier Fact Sheet

The 21st Century Cures Act (Cures Act) includes a provision that calls for the development of a new home infusion therapy (HIT) benefit under Medicare Part B. The benefit will be provided by home infusion therapy suppliers and includes the professional services for beneficiaries receiving home infusion therapy through a pump that is an item of durable medical equipment (DME). Medicare covers certain infusion drugs under Part B when the drug requires infusion by a pump.

In the 2019 and 2020 Home Health Payment Rate Update rules, the Centers for Medicare & Medicaid Services (CMS) finalized the coverage and payment policies related to the new home infusion therapy benefit. The CY 2021 Home Health Payment Rate Update rule finalized the provider enrollment requirements for the home infusion therapy benefit.

Provisions of the Cures Act requires permanent implementation of the new benefit to begin on January 1, 2021. Professional services related to the provision of Part B infusion drugs will no longer be covered under the Medicare home health benefit as of this date.

Structure

- New benefit under Medicare Part B
- New supplier designation – Home Infusion Therapy Supplier. A home infusion therapy supplier must be accredited by a Medicare approved accrediting organization (AO).
- The new benefit provides coverage for professional services associated with drugs infused in the home on a pump that is an item of DME
- Applies only to Part B infusion drugs.
 - a home infusion drug is 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,
- A full list of Part B drugs effective for 2021 are listed on Appendix A.
- A qualified home infusion therapy supplier is defined as a:
 - pharmacy,
 - physician,
 - Other provider of services or supplier licensed by the state where service are provided (home health and hospice providers may enroll as a home infusion therapy supplier).

Requirements under the new benefit include:

- Compliance with §486.500-525 and §414.1500-1550 (see Appendix B and Appendix C)
- A plan of care for the professional services must be established and reviewed by a physician.
- The patient must be under the care of a physician, nurse practitioner, or physician assistant.
- Remote monitoring, could include monitoring via telephone
- 24/7 availability

Physician Notification of Infusion Therapy

- Before physicians write the POC for HIT services they must first notify the patient of the treatment options available for the furnishing of infusion therapy (home or otherwise) under Medicare Part B - (such as home, physician's office, hospital outpatient department). The Medicare Part B HIT services benefit requires that prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan of care shall provide notification of the patient's available options. Physicians may use multiple forms, manners, and frequencies to do this.

Professional services (e.g. nursing) include:

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

Enrollment

- Must be accredited by a Medicare approved AO in order to enroll in Medicare as a HIT supplier.
- Comply with the conditions for payment and coverage under §414.1500- 1550 and §486.500-525
- Complete Form CMS-855B application
- A current NPI may be used

- HIT supplier will need to be written in on the paper form CMS 855B under “other, supplier type”. HIT supplier is listed as an option in the CMS 855B PECOS application.
- All applicants are subject to the Medicare enrollment application fee (2020 -\$595.00).
- Submit the CMS 855B application to your A/B MAC (see Appendix D)
- HIT suppliers are in a limited risk level category for screening.
- The HIT supplier is required to enroll in each state in which it has an accredited practice location.
- Applicants have the same appeal rights for enrollment denials and revocations as other Medicare enrollees.
- Effective date for enrollment is the later of (1) The date of filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the supplier first began furnishing services at a new practice location.
- May be participating or non-participating

Payment

- The professional services are billed on a professional claim CMS-1500/837P
- A single payment is made for each day a visit is made in the home and on the day the drug is infused. The drug does not need to be infused during the visit.
- Drugs are grouped into three categories based on infusion complexity and resource utilization
- Each drug category is divided into an initial visit payment rate and subsequent visit payment rate.
- The initial visit is reimbursed at a higher payment rate than subsequent visits. (see Appendix B)

Oversight

- The AO is responsible for setting the quality standards, accrediting HIT suppliers, and for the ongoing oversight of HIT suppliers.
- The AO must meet specific criteria established by CMS in order to become an AO for home infusion therapy supplies.

Coordination with Home Health

- Home health patients may receive HIT professional services by a HIT supplier and skilled services under the home health benefit concurrently.
- Only a HIT supplier may bill for HIT professional services
- If a patient is under a home health plan of care, and a home health visit is furnished that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS and billed on the home health claim.
- If the home health agency (HHA) providing services under the Medicare home health benefit is also the same entity furnishing services as the qualified HIT supplier, and a home visit is exclusively for the purpose of furnishing home infusion therapy services, the HHA would submit a claim for payment as a HIT supplier and receive payment under the home infusion therapy services benefit.
- If the HHA providing services under the Medicare home health benefit is also the same entity furnishing services as the qualified home infusion therapy supplier and the home visit includes the provision of home health services in addition to, and separate from, items and services related to home infusion therapy, the HHA would submit both a home health claim and a home infusion therapy services claim, and must separate the time spent performing services covered

under the HH PPS from the time spent performing services covered under the home infusion therapy services benefit.

APPENDIX A : Medicare Part B Infusion Drugs and Categories / G codes and Rates

Category 1	
J-Code	Description
J0133	Acyclovir, 5 mg
J0285	Amphotericin b, 50 mg
J0287	Amphotericin b lipid complex, 10 mg
J0288	Amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Amphotericin b liposome, 10 mg
J0895	Deferoxamine mesylate, 500 mg
J1170	Hydromorphone, up to 4 mg
J1250	Dobutamine hydrochloride, per 250 mg
J1265	Dopamine hcl, 40 mg
J1325	Epoprostenol, 0.5 mg
J1455	Foscarnet sodium, per 1000 mg
J1457	Gallium nitrate, 1 mg
J1570	Ganciclovir sodium, 500 mg
J2175	Meperidine hydrochloride
J2260	Milrinone lactate, 5 mg
J2270	Morphine sulfate, up to 10 mg
J3010	Fentanyl citrate, 0.1 mg
J3285	Treprostinil
Category 2	
J-Code	Description
J1555 JB	Cuvitru, 100 mg
J1558 JB	Xembify, 100mg
J1559 JB	hizentra 100mg
J1561 JB	Gamunex-c/(Gammaked), non-lyophilized, 500 mg
J1562 JB	Vivaglobin, 100 mg
J1569 JB	Gammagard, non-lyophilized, 500 mg
J1575 JB	Hyqvia, 100 mg
J7799 JB	This NOC code may be used to identify the subcutaneous immune globulin (cutaquist)
Category 3	
J-Code	Description
J9000	Doxorubicin hydrochloride, 10 mg
J9039	Blinatumomab, 1 microgram
J9040	Bleomycin sulfate, 15 units
J9065	Cladribine, per 1 mg
J9100	Cytarabine, 100 mg
J9190	Fluorouracil, 500 mg
J9360	Vinblastine sulfate, 1 mg
J9370	Vincristine sulfate, 1 mg

APPENDIX B: Home Infusion Therapy Services Payment

§414.1500 Basis, purpose, and scope.

This subpart implements section 1861(iii) of the Act with respect to the requirements that must be met for Medicare payment to be made for home infusion services furnished to eligible beneficiaries.

§414.1505 Requirement for payment.

In order for home infusion therapy services to qualify for payment under the Medicare program the services must be furnished to an eligible beneficiary by, or under arrangements with, a qualified home infusion therapy supplier that meets the following requirements:

(a) The health and safety standards for qualified home infusion therapy suppliers at §486.520(a) through (c) of this chapter.

(b) All requirements set forth in §§414.1510 through 414.1550.

(c) The home infusion therapy supplier must be enrolled in Medicare consistent with the provisions of §424.68 and part 424, subpart P of this chapter.

§414.1510 Beneficiary qualifications for coverage of services.

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

(a) *Under the care of an applicable provider.* 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) *Under a physician plan of care.* The beneficiary must be under a plan of care that meets the requirements for plans of care specified in §414.1515.

§414.1515 Plan of care requirements.

(a) *Contents.* The plan of care must contain those items listed in §486.520(b) of this chapter that specify the standards relating to a plan of care that a qualified home infusion therapy supplier must meet in order to participate in the Medicare program.

(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

Administration G codes	Initial visit	Rate	Subsequent visit	Rate
Category 1	G0088	\$188.85	G0068	\$156.83
Category	G0089	\$256.83	G0069	\$213.37
Category	G0090	\$319.80	G0070	\$265.57

that the most appropriate level of services is furnished.

(c) *Plan of care signature requirements.* 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.

PAYMENT SYSTEM

§414.1550 Basis of payment.

(a) *General rule.* For home infusion therapy services furnished on or after January 1, 2021, Medicare payment is made on the basis of 80 percent of the lesser of the following:

(1) The actual charge for the item or service.

(2) The fee schedule amount for the item or service, as determined in accordance with the provisions of this section.

(b) *Unit of single payment.* A unit of single payment is made for items and services furnished by a qualified home infusion therapy supplier per payment category for each infusion drug administration calendar day, as defined at §486.505 of this chapter.

(c) *Initial establishment of the payment amounts.* In calculating the initial single payment amounts for CY 2021, CMS determined such amounts using the equivalent to 5 hours of infusion services in a physician's office as determined by codes and units of such codes under the annual fee schedule issued under section 1848 of the Act as follows:

(1) *Category 1.* (i) Includes certain intravenous infusion drugs for therapy, prophylaxis, or diagnosis, including antifungals and antivirals; inotropic and pulmonary hypertension drugs; pain management drugs; chelation drugs; and other intravenous drugs as added to the durable medicare equipment local coverage determination (DME LCD) for external infusion pumps.

(ii) Payment equals 1 unit of 96365 plus 4 units of 96366.

(2) *Category 2.* (i) Includes certain subcutaneous infusion drugs for therapy or prophylaxis, including certain subcutaneous immunotherapy infusions.

(ii) Payment equals 1 unit of 96369 plus 4 units of 96370.

(3) *Category 3.* (i) Includes intravenous chemotherapy infusions, including certain chemotherapy drugs and biologicals.

(ii) Payment equals 1 unit of 96413 plus 4 units of 96415.

(4) *Initial visit.* (i) For each of the three categories listed in paragraphs (c)(1) through (3) of this section, the payment amounts are set higher for the first visit by the qualified home infusion therapy supplier to initiate the furnishing of home infusion therapy services in the patient's home and lower for subsequent visits in the patient's home. The difference in payment amounts is a percentage based on the relative payment for a new patient rate over an existing patient rate using the annual

physician fee schedule evaluation and management payment amounts for a given year and calculated in a budget neutral manner.

(ii) The first visit payment amount is subject to the following requirements if a patient has previously received home infusion therapy services:

(A) The previous home infusion therapy services claim must include a patient status code to indicate a discharge.

(B) If a patient has a previous claim for HIT services, the first visit home infusion therapy services claim subsequent to the previous claim must show a gap of more than 60 days between the last home infusion therapy services claim and must indicate a discharge in the previous period before a HIT supplier may submit a home infusion therapy services claim for the first visit payment amount.

(d) *Required payment adjustments.* The single payment amount represents payment in full for all costs associated with the furnishing of home infusion therapy services and is subject to the following adjustments:

(1) An adjustment for a geographic wage index and other costs that may vary by region, using an appropriate wage index based on the site of service of the beneficiary.

(2) Beginning in 2022, an annual increase in the single payment amounts from the prior year by the percentage increase in the Consumer Price Index (CPI) for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

(3)(i) An annual reduction in the percentage increase described in paragraph (d)(2) of this section by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(ii) The application of the paragraph (c)(3)(i) of this section may result in the both of the following:

(A) A percentage being less than zero for a year.

(B) Payment being less than the payment rates for the preceding year.

(e) *Medical review.* All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Plan of care requirements.

(3) Medical necessity determinations.

APPENDIX C: Requirements for Home Infusion Therapy Suppliers

§486.500 Basis and scope.

Section 1861(s)(2)(iii) of the Act requires the Secretary to establish the conditions that home infusion therapy suppliers must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients.

§486.505 Definitions.

As used in §§486.520 and 486.525:

Applicable provider means a physician, a nurse practitioner, and a physician assistant.

Home means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, CAH, or SNF as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Home infusion drug means a parental 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 durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

Infusion drug administration calendar day means 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.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

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

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

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

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

[83 FR 56630, Nov. 13, 2018, as amended at 84 FR 60646, Nov. 8, 2019]

STANDARDS FOR HOME INFUSION THERAPY

§486.520 Plan of care.

The qualified home infusion therapy supplier ensures the following:

(a) All patients must be under the care of an applicable provider.

(b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.

(c) The plan of care for each patient must be periodically reviewed by the physician.

§486.525 Required services.

(a) The qualified home infusion therapy supplier must provide the following services on a 7-day-a-week, 24-hour-a-day basis in accordance with the plan of care:

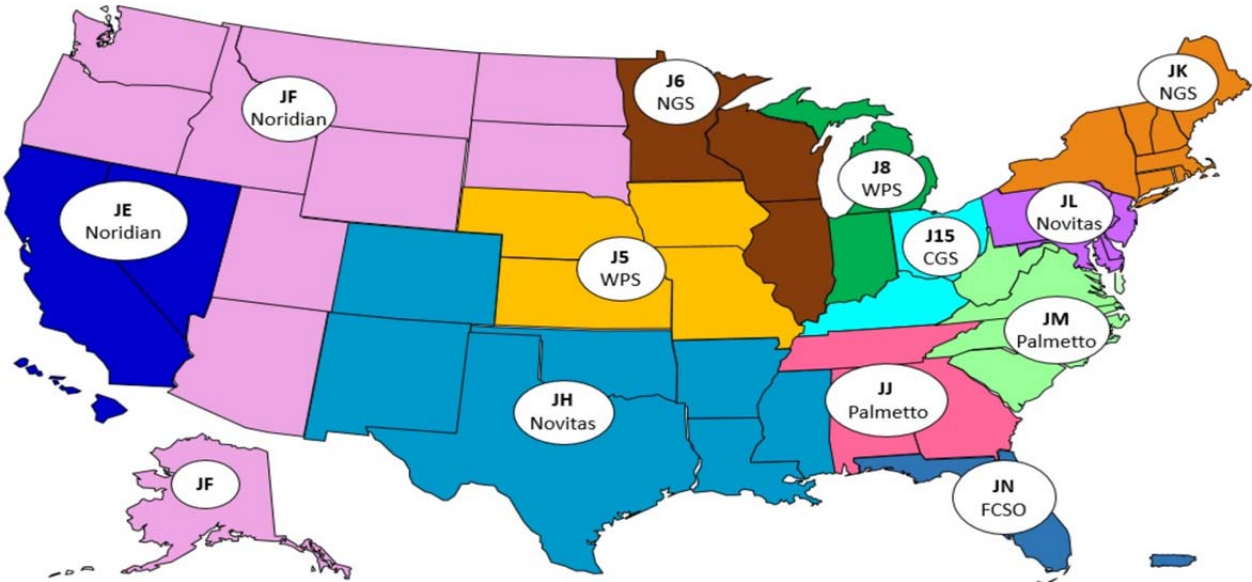
(1) Professional services, including nursing services.

(2) Patient training and education not otherwise paid for as durable medical equipment as described in §424.57(c)(12) of this chapter.

(3) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

(b) 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.

APPENDIX D: A/B MAC Jurisdictions – Map and List of States



MAC Jurisdiction	Processes Part A & Part B Claims for the following states:	MAC
DME A	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont	Noridian Healthcare Solutions, LLC
DME B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin	CGS Administrators, LLC
DME C	Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, U.S. Virgin Islands	CGS Administrators, LLC
DME D	Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana	Noridian Healthcare Solutions, LLC
5	Iowa, Kansas, Missouri, Nebraska	Wisconsin Physicians Service Government Health Administrators
6	Illinois, Minnesota, Wisconsin **HH + H for the following states: Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Michigan, Minnesota, Nevada, New Jersey, New York, Northern Mariana Islands, Oregon, Puerto Rico, US	National Government Services, Inc.

8	Indiana, Michigan	Wisconsin Physicians Service Government Health Administrators
15	Kentucky, Ohio **HH + H for the following states: Delaware, District of Columbia, Colorado, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota,	CGS Administrators, LLC
E	California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
F	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	Noridian Healthcare Solutions, LLC
H	Arkansas, Colorado, New Mexico, Oklahoma, Texas,	Novitas Solutions, Inc.
J	Alabama, Georgia, Tennessee	Palmetto GBA, LLC
K	Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont **HH + H for the following states: Connecticut, Maine,	National Government Services, Inc.
L	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia)	Novitas Solutions, Inc.
M	North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) **HH + H for the following states: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana,	Palmetto GBA, LLC
N	Florida, Puerto Rico, U.S. Virgin Islands	First Coast Service Options, Inc.

****Also Processes Home Health and Hospice claims**

Resources:

Medicare Part B Home Infusion Therapy Services With The Use of Durable Medical Equipment
<https://www.cms.gov/files/document/se19029.pdf>

Billing for Home Infusion Therapy Services On or After January 1, 2021
<https://www.cms.gov/files/document/r10463cp.pdf>

Update to Chapter 10 of Publication (Pub.) 100-08 - Enrollment Policies for Home Infusion Therapy (HIT) Suppliers <https://www.cms.gov/files/document/mm11954.pdf>

Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements
<https://public-inspection.federalregister.gov/2020-24146.pdf>