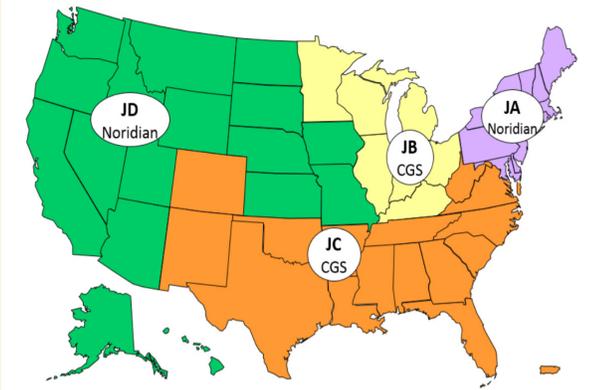
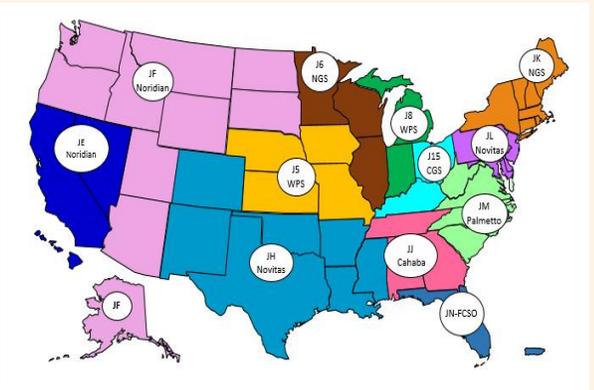


**Based on information available Oct. 1, 2020. Subject to change based on final rule.*

	Temporary Transitional (2019-2020)	Permanent (2021 and Beyond)
Who can bill	Licensed pharmacy enrolled in Part B Durable Medical Equipment (DME) program to provide items in the external infusion pump product category.	Pharmacy, physician, home health, or other state-licensed provider.
Accreditation	No additional accreditation is required, supplier must ensure that home visits meet state licensure requirements.	Separate accreditation for home infusion therapy (HIT) services. Accrediting Organizations: Joint Commission, Accreditation Commission for Health Care, URAC, Community Health Accreditation Partner, National Association of Boards of Pharmacy.
Enrollment	Durable Medical Equipment Medicare Administrative Contractor (DME MAC)	A/B Medicare Administrative Contractor (MAC) Obtain a new National Provider Identifier (NPI) for HIT service enrollment. Enroll with each of the A/B MACs you plan to provide HIT services (based on beneficiary address) for Provider Transaction Access Number (PTAN) assignment.
		
Covered drugs	DME-infused drugs administered intravenously, or subcutaneously over 15-minutes or more, identified in the 2018 Balanced Budget Act (BBA).	DME-infused drugs administered intravenously, or subcutaneously over 15 minutes. Same as transitional with the following removed: <ul style="list-style-type: none"> • Hizentra® (J1559)* • Morphine, PF (J2274) • Ziconotide® (J2278) • Floxuridine® (J9200) And Xembify added <i>See full listing of HIT DME infused drugs on page 8.</i>
Eligible patients	Patients receiving an applicable DME-infused drug who are not open to a home health episode.	Patients receiving an applicable DME-infused drug. Patients are not required to be homebound.
When payable	When a skilled professional is in the patient's home within 30-day of the applicable drug being dispensed.	When a skilled professional is in the patient's home within 30-days of an applicable drug being dispensed and on a day that an applicable drug is administered.
Who may order services/sign the plan of care (POC)	Applicable provider (physician, nurse practitioner, or physician's assistant)	Physician only

**If passed, the Preserving Patient Access to Home Infusion Coverage Act (S. 3457, H.R. 6218) would maintain coverage for Hizentra under the permanent benefit.*

	Temporary Transitional (2019-2020)	Permanent (2021 and Beyond)
Description of covered services	<p>Nothing in the rule prohibits pharmacists from providing a service that falls within their scope of practice. However, services are only billed on days when a skilled professional is in the home.</p> <p>The skilled services must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel.</p> <ul style="list-style-type: none"> • Nursing services • 24/7 support • Training and education according to existing accreditation standards • Remote monitoring and monitoring by pharmacists and nurses to assess response to treatment, drug complications, adverse reactions, and compliance. 	<p>Nothing in the rule prohibits pharmacists from providing a service that falls within their scope of practice. However, services are only billed on days when a skilled professional is in the home.</p> <p>The skilled services must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. All services must be within the practitioner's scope of practice.</p> <ul style="list-style-type: none"> • Nursing services • 24/7 support • Monitoring/remote monitoring whether provided by a pharmacist or nurse • Communication about changes in therapy <ul style="list-style-type: none"> • Assessing compliance • Response to therapy • Communication about changes in therapy • Training and education on vascular access device (VAD) <ul style="list-style-type: none"> • Hygiene <ul style="list-style-type: none"> • Handling dislodgment or occlusion • Signs and symptoms of infection • Dressing changes and site care • Patient assessment and evaluation whether provided by a pharmacist or nurse <ul style="list-style-type: none"> • Adverse events and complications of infusion • Evaluation of careiver support • Medication review • Medication and disease management whether provided by a pharmacist or nurse <ul style="list-style-type: none"> • Self-monitoring instruction • Lifestyle and nutrition modification • Education on drug, side-effects, drug interactions, adverse events and infusion-related reactions • Handling spills • Education on goals • Pre-meds and inspecting meds prior to use
Intersection with Part A home health	<p>HIT nursing services can be provided either through Part A home health episode, or Part B HIT benefit. HIT provider may only bill for services when a patient is not open to a home health episode.</p>	<ul style="list-style-type: none"> • See page 8 for listing of DME-infused drugs that the HIT services benefit applies to. • HIT services are wholly separate from Medicare Part A home health episodic care and can only be billed by an accredited/enrolled home infusion therapy service supplier. • The homebound requirement does not apply to Part B HIT services. • Home health agencies (HHAs) can enroll as Part B HIT services suppliers and bill directly to Part B for infusion-related services. • For patients receiving non-infusion-related Part A home health in addition to Part B infusion nursing, the Medicare certified HHA and the Part B HIT services supplier must bill each service separately. If the HHA and HIT services supplier are the same entity, then the services are billed separately to each benefit. • HHAs enrolled as Part B HIT services suppliers may contract with the home infusion pharmacy for pharmacist professional services provided as part of the bundled payment paid when a skilled professional is in the home. • Home infusion pharmacies enrolled as HIT services suppliers can provide nursing services directly or subcontract with another state licensed nursing agency.
DME items	<p>Continue to bill the DME MAC for covered drugs, equipment, and supplies.</p>	<p>Continue to bill the DME MAC for covered drugs, equipment, and supplies.</p>
Plan of care (POC) elements	<ul style="list-style-type: none"> • Specific medication, dosage, and frequency • Type, amount, duration of HIT services • Services specific to patient's needs 	<ul style="list-style-type: none"> • Specific medication, dosage, and frequency • Type, amount, duration of HIT services • Frequency of services • Health care professional performing the services <p>See example of Medicare Part B HIT services plan of care (POC) on page 6</p>

HCPCS	Note	Short Descriptor	Allowable (estimate)
Category 1			
G0088	Initial	Adm IV drug 1st home visit.	\$255.25
G0068	Subsequent	Adm IV infusion drug in home.	\$153.54
Category 2			
G0089	Initial	Adm SubQ drug 1st home visit.	\$357.44
G0069	Subsequent	Adm SQ infusion drug in home.	\$215.00
Category 3			
G0090	Initial	Adm IV chemo 1st home visit.	\$422.70
G0070	Subsequent	Adm of IV chemo drug in home.	\$254.26

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 will likely use multiple forms, manners, and frequencies to do this.

For example, physicians may verbally discuss treatment options during the visit and annotate in the medical record before establishing the infusion plan or provide the options in writing during visit or as part of hospital discharge. Physicians may retain written attestation that all options were discussed. The frequency of discussing options could vary based on a routine scheduled visit or according to the patient's clinical needs. Future policy will continue to be developed through notice-and-comment rulemaking for CY 2021 and beyond.

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Preserving Patient Access to Home Infusion Act

S. 3457 / H.R. 6218

Help Home Infusion Patients Lead Healthy, Independent Lives



The legislation (H.R. 6218, S. 3457) was introduced in March 2020 and will accomplish the following if passed:

- Require CMS to pay home infusion providers for professional services each day the drug is administered.
- Remove the requirement that a skilled professional be present in the home for billing to occur.
- Explicitly acknowledge pharmacy professional services.
- Keep all drugs in the benefit that were part of the transitional program (i.e. Hizentra)

www.bit.ly/nhia-pitch-in

Medicare HIT POC Required Elements for 2021

The 21st Century Cures Act defines “home infusion therapy” (HIT) as professional services, including:

- Nursing services
- Training and education not covered otherwise under the DME benefit
- Remote monitoring, and other monitoring services
- 24/7 support

Home infusion therapy must be furnished by a qualified HIT provider and furnished in the individual’s home. The individual must:

- Be under the care of an applicable provider (that is physician, nurse practitioner, or physician’s assistant); and
- Have a plan of care established and periodically **reviewed by a physician** in coordination with the furnishing of home infusion drugs under Part B, that prescribes the type, amount, and duration of infusion therapy services that are to be furnished.¹

The act also requires HIT providers to be accredited by a CMS-approved accrediting organization.

Required Elements of the Medicare HIT Plan of Care

- Medication name, dose, and frequency
- Type, amount, duration, and frequency of the services to be provided
- Health care professional performing each service
- Physician signature

Covered Services

The skilled services must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. All services must be within the practitioner’s scope of practice.

- Infusion-related nursing services
 - Providers **do not need** to be Medicare certified home health providers in order to provide Part B HIT nursing and to bill G codes
 - Patients **do not need** to be homebound to qualify for Part B HIT nursing services
- 24/7 support
- Monitoring/remote monitoring
- Communication about changes in therapy
 - Assessing compliance (monitoring medication adherence)
 - Response to therapy
- Training and education on VAD, including but not limited to:
 - Hand hygiene and infection control/prevention practices
 - VAD care and maintenance
 - VAD complication management i.e. dislodgement or occlusion
 - Signs and symptoms of infection
- Patient assessment and evaluation (whether provided by a pharmacist or nurse, in person or remotely) for:
 - Adverse events and complications of infusion
 - Evaluation of caregiver support
 - Medication review
 - Review of labs results
 - Response to treatment
 - Physical assessment
 - Functional limitations
 - VAD care i.e. dressing change, lab draw
- Medication and disease state management
 - Instruction for self-monitoring for proper response to therapy and adverse events
 - Lifestyle and nutrition counseling
 - Education on medication, side effects, drug interactions, adverse and infusion-related reactions
 - Medication safe handling i.e. spills, medical waste, inspection, refrigeration requirements
 - Collaborative development of patient centered goals of therapy
 - Pre-medication regimen if indicated

References:

1. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices-Items/CMS-1711-FC>
2. <https://www.federalregister.gov/documents/2019/11/25/2019-25430/medicare-program-application-from-accreditation-commission-for-health-care-for-initial-cms-approval>
3. *INS Infusion Therapy Standards of Practice*, <https://source.yiboshi.com/20170417/1492425631944540325.pdf>
4. https://www.nhia.org/documents/position_paper.pdf
5. *MM11750 New Supplier Specialty Code for Home Infusion Therapy Services*, <https://www.cms.gov/files/document/mm11750.pdf>
6. *Medicare Administrative Contractors*, <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-the-MACs>
7. *MM11880 Billing for Home Infusion Therapy Services on or After January 1, 2021*, <https://www.cms.gov/files/document/mm11880.pdf>

Example Medicare B HIT Plan of Care

Patient Name: _____ **DOB:** _____ **MRN:** _____
Address: _____ **City:** _____ **State:** _____ **Phone:** _____
Physician Name: _____ **Phone:** _____

Allergies: _____
Complete Medication List: _____

Name	Dose	Route	Frequency	Start	Stop
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____

Primary Diagnosis(es): _____
Secondary Diagnosis(es): _____

Home Infusion Orders
Home Infusion Medication (name/dose/route/frequency): _____
MOA: Equipment/Supplies: _____
Therapy Start Date: _____ **Therapy End Date:** _____

Vascular access device (VAD) Orders: _____
Flush protocol: _____
NS _____ ml **Instructions:** _____
Heparin _____ u/ml, _____ ml **Instructions:** _____
Other: _____

Lab Orders: _____ **Frequency:** _____

Pharmacist Professional Services Frequency: Continuously and with each dispensing of DME infused medication.

- 24/7 support;
- Therapy evaluation, design, and preparation ensuring compatibility with VAD, external infusion pump and supplies, patient ability, and therapy goals;
- Review, develop, modify the monitoring plan;
- Perform medication review for all drug interactions, contraindications, and therapy duplication;
- Provide education for home infusion medication side effects, interactions, adverse reactions, and infusion-related reactions;
- Remote monitoring for response to therapy, side effects, administration-related reactions, VAD events.

Nursing services:

Home visits _____ per week up to _____ visits for training, instruction, and monitoring of home infusion medication administration, and VAD care.

Patient Care, Instruction, Monitoring and Assessments:

Review of patient medical history	Initial and ongoing
Physical, mental, and environmental assessment	Initial and ongoing
Infection control, hand hygiene, VAD and self-care	Initial and ongoing
VAD evaluation, care, and maintenance	Initial and ongoing
Medication administration, safe handling, and monitoring	Initial and ongoing
Response and adherence to treatment	Initial and ongoing
Monitoring for drug adverse events	Initial and ongoing
Lab draws	As ordered by physician

Functional limitations: _____
Special dietary or nutritional needs: _____
Safety concerns: _____

Intervention(s):

- Based on therapy

Goals

- Resolution of primary problem(s)
- Prevent VAD associated complications
- Prevention of ADE

Review of this plan of care will be done by the client's/patient's physician on a frequency as outlined by this organization's policies and procedures. Physician review will determine that the required services are still required and being received, are appropriate, and are effective.

Review of this plan of care by the home infusion services supplier will be done at a minimum with each refill, at client/patient/prescriber request, with any changes in care, or as designated by the organizations' policies and procedures.

Clinician Signature: _____ **Date:** _____

Physician Signature: _____ **Date:** _____

Medicare B HIT Plan of Care User Guide

Patient Demographics and Provider Information

- Basic demographics for the patient including start of care date, name, DOB, address, phone, weight, height, and prescribing provider information

Allergies and Medication list

- Detailed list of all allergies including drug, food, and other
- A complete medication including oral medications and supplements

Diagnosis

- Primary diagnosis for the medication being provided in the home setting
- Secondary diagnoses are the remaining diagnoses the patient has documented in the medical record

Orders

- Provider orders for the home infusion therapy medication including dose, route, frequency, method of administration via ambulatory infusion pump
- Include the start and stop date for the medication
- Vascular access device care and maintenance orders i.e. flushing protocol

Pharmacist Services

- Document professional services related to individualized care plan and monitoring, adverse event monitoring, drug utilization review, lab monitoring, therapy recommendations in collaboration with prescribing physician, side effect monitoring, and patient education frequency

Nursing Services

- Document the professional nursing services the nurse will perform in the management of the therapy ordered, including specific activities and the frequency associated with those activities including, but not limited to: visit number and frequency, all monitoring, teaching, and assessment activities, lab draws, VAD maintenance, interventions, and goals of therapy

Signature Requirements

- Medicare requires the POC to be signed by a physician. Refer to HIT accreditation organization standards for preparer (infusion supplier) signature requirements

List of DME Infused Drugs Associated with the 2021 Permanent HIT Service Benefit

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, 1 mg
Category 2	
J-Code	Description
J1555 JB	Cuvitru, 100 mg
J1558 JB	Xembify, 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
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

While the HIT services for the above drugs were covered under the 2019/2020 transitional benefit, HIT services do not apply for the permanent benefit: Hizentra® (J1559), Morphine, PF (J2274), Ziconotide® (J2278), Floxuridine® (J9200), coverage for these drugs, and related equipment and supplies, remains under the DME benefit.