CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10463	**Date: November 13, 2020**
	Change Request 11880

Transmittal 10269, dated August 7, 2020, is being rescinded and replaced by Transmittal 10463, dated, November 13, 2020 to revise Business Requirement 11880.04.3 and to add Business Requirements 11880.04.2.2 through 11880.04.2.11 in Publication 100-04 only. This correction does not change any instructions in Publication 100-02. In addition, this correction adds a new Attachment (B) titled, Home Infusion Therapy (HIT) Services Payment File Layout. All other information remains the same.

SUBJECT: Billing for Home Infusion Therapy Services On or After January 1, 2021

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is guidance and claims processing systems changes necessary to implement of Section 5012(d) of the 21st Century Cures Act, and to detail necessary changes to those systems and processes to design business requirements for a future implementation CR. These payments begin January 1, 2021.

EFFECTIVE DATE: January 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2021

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	15/Table of Contents
N	15/320/Home Infusion Therapy Services
N	15/320/320.1/General Requirements for Payment of Home Infusion Therapy Services
N	15/320/320.2/Home Infusion Therapy Services Benefit is Separate from DME Benefit
N	15/320/320.3/Qualified Home Infusion Therapy Suppliers
N	15/320/320.4/Patient Eligibility for Home Infusion Therapy
N	15/320/320.4/320.4.1/Home Infusion Therapy Services for Homebound Patients
N	15/320/320.5/Plan of Care Requirements
N	15/320/320.5/320.5.1/Notification of Available Infusion Therapy Options
N	15/320/320.5/320.5.2/Plan of Care Periodic Review and Provider Coordination
N	15/320/320.6/Professional Services, Including Nursing Services, for Home Infusion Therapy
N	15/320/320.6/320.6.1/Home Infusion Therapy Services Training and Education
N	15/320/320.6/320.6.2/Remote Monitoring and Monitoring Services
N	15/320/320.7/Home Infusion Therapy Drugs
N	15/320/320.7/320.7.1/Determining Qualifying Home Infusion Drugs
N	15/320/320.8/Payment for Home Infusion Therapy Services
N	15/320/320.8/320.8.1/Home Infusion Drug Payment Categories
N	15/320/320.8/320.8.2/Infusion Drug Administration Calendar Day and Unit of Single Payment
N	15/320/320.8/320.8.3/Initial Visits and Subsequent Visits for Home Infusion Therapy Services
N	15/320/320.9/Medical Review

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:
Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 10463	Date: November 13, 2020	Change Request: 11880

Transmittal 10269, dated August 7, 2020, is being rescinded and replaced by Transmittal 10463, dated, November 13, 2020 to revise Business Requirement 11880.04.3 and to add Business Requirements 11880.04.2.2 through 11880.04.2.11 in Publication 100-04 only. This correction does not change any instructions in Publication 100-02. In addition, this correction adds a new Attachment (B) titled, Home Infusion Therapy (HIT) Services Payment File Layout. All other information remains the same.

SUBJECT: Billing for Home Infusion Therapy Services On or After January 1, 2021

EFFECTIVE DATE: January 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2021

I. GENERAL INFORMATION

A. Background: Effective January 1, 2021, section 5012 of the 21st Century Cures Act (Pub. L. 114–255), which added sections 1861(s)(2)(GG) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit. Section 1861(iii) of the Act establishes certain provisions related to home infusion therapy with respect to the requirements that must be met for Medicare payment to be made to qualified home infusion therapy suppliers. These provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services; outline beneficiary qualifications and plan of care requirements; and establish who can bill for payment under the benefit.

The Medicare home infusion therapy 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.

B. Policy: Effective for dates of service on or after January 1, 2021, the Medicare home infusion therapy 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.

Home infusion therapy services means the items and services furnished by a qualified home infusion therapy supplier, which are furnished in the individual's home. Payment is for an "infusion drug administration calendar day," which 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.

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 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.

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

The home infusion therapy services payment is intended to cover the professional services needed for the administration of certain home infusion drugs covered as supplies necessary for the effective use of external infusion pumps. This payment separately and explicitly pays for the services related to the administration of the drugs identified on the DME LCD for External Infusion Pumps, when such services are furnished in the individual’s home.

Section 1861(iii)(3)(C) of the Act defines “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 durable medical equipment (as defined in section 1861(n) of the Act). Such term does not include insulin pump systems or self-administered drugs or biologicals on a self-administered drug exclusion list.

Home infusion drugs are assigned to three payment categories, as determined by the HCPCS J-code. Payment category 1 includes certain intravenous antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, chelation drugs. Payment category 2 includes subcutaneous immunotherapy and other certain subcutaneous infusion drugs. Payment category 3 includes certain chemotherapy drugs.

CMS has established a single payment amount for each of the three categories for professional services furnished for each infusion drug administration calendar day. Each payment category will be paid at amounts in accordance with infusion codes and units for such codes under the physician fee schedule for each infusion drug administration calendar day in the individual’s home for drugs assigned to such category. The payment amounts are equal to 5 hours of infusion therapy in a physician’s office.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
11880 - 02.1	Contractors shall be advised that effective for claims with dates of service on or after January 1, 2021, a separate payment for home infusion therapy services will be made under the permanent home infusion therapy services benefit to qualified home infusion suppliers. The 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		X		X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	under the durable medical equipment benefit), remote monitoring, and monitoring services for the provision of home infusion therapy services and 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.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11880 - 02.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.		X		X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Yvette Cousar, 410-786-2160 or Yvette.Cousar@cms.hhs.gov ((Billing Requirements)) , Cheryl Gilbreath, 410-786-7919 or Cheryl.Gilbreath@cms.hhs.gov ((Benefit Policy))

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

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(Rev. 10463, 11-13-20)

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320 - Home Infusion Therapy Services
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

Effective January 1, 2021, section 5012 of the 21st Century Cures Act (Pub. L. 114–255), which added sections 1861(s)(2)(GG) and 1861(iii) of the Act, established a new Medicare home infusion therapy services benefit. Section 1861(iii) of the Act establishes certain provisions related to home infusion therapy with respect to the requirements that must be met for Medicare payment to be made to qualified home infusion therapy suppliers. These provisions serve as the basis for determining the scope of the home infusion drugs eligible for coverage of home infusion therapy services; outline beneficiary qualifications and plan of care requirements; and establish who can bill for payment under the benefit.

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.

320.1 - General Requirements for Payment of Home Infusion Therapy Services
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

The home infusion therapy services must be furnished to an eligible beneficiary by, or under arrangement with, a qualified home infusion therapy supplier that meets the health and safety standards for qualified home infusion therapy suppliers at 42 CFR 486 Subpart I, and all requirements set forth in 42 CFR 414 Subpart P.

As a condition for payment, qualified home infusion therapy suppliers must ensure that a beneficiary meets certain eligibility criteria for coverage of services, as well as ensure that certain plan of care requirements are met.

320.2 - Home Infusion Therapy Services Benefit is Separate from DME Benefit
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

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 home infusion therapy services. 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.

For DME infusion pumps, the DME benefit covers the infusion drugs and other supplies and services necessary for the effective use of the pump, but does not explicitly require or pay separately for any associated skilled professional services beyond what is necessary for teaching the patient and/or caregiver how to operate the equipment in order to administer the infusion safely and effectively in the patient's home (42 CFR 424.57(c)(12)).

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. Further billing information can be found in Publication 100-04, Chapter 32, Section 411.

320.3 - Qualified Home Infusion Therapy Suppliers
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

Section 1861(iii)(3)(D)(i) of the 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.

The qualified home infusion therapy supplier must:

A. *Furnish home infusion therapy services to individuals with acute or chronic conditions requiring administration of home infusion drugs;*
B. *Ensure the safe and effective provision and administration of home infusion therapy services on a 7-day-a-week, 24-hour a-day basis;*
C. *Be accredited by an organization designated by the Secretary; and meet such other requirements as the Secretary determines appropriate.*

The supplier may subcontract with a pharmacy, physician, other qualified supplier or provider of medical services, in order to meet these requirements. Additionally, section 1861(u) of the Act defines "provider of services" to mean a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of sections 1814(g) and 1835(e) of the Act, a fund. Therefore, any of the previously noted entities who meet the Medicare accreditation requirements for home infusion therapy suppliers is eligible to enroll as a qualified home infusion therapy supplier.

In the case that a home health agency also becomes accredited as a home infusion therapy supplier, the HHA would continue to meet the requirements under the Home Health Conditions of Participation (CoPs) as well as the home infusion therapy supplier requirements as set out in 42 CFR 486 Subpart I, of which DME services, including pharmacy services associated with the preparation and dispensing of home infusion drugs are not included.

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 part of this specific home infusion therapy services benefit.

320.4 - Patient Eligibility for Home Infusion Therapy
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

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.*

Home infusion services must be furnished in the patient's home, which means the place of residence as defined for purposes of section 1861(n) of the Act used as the home of an individual, including an institution that is used as a home (excluding hospitals, critical access hospitals, and skilled nursing facilities as defined in section 1819(a)(1) of the Act).

320.4.1 - Home Infusion Therapy Services for Homebound Patients
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

A beneficiary is not required to be homebound in order to receive home infusion therapy services. However, there may be instances where a beneficiary under a home health plan of care also requires home infusion therapy services.

If a patient receiving home infusion therapy is also under a home health plan of care, and receives a visit that is unrelated to home infusion therapy, 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.

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

If the home visit includes the provision of other home health services in addition to, and separate from, home infusion therapy services, the home health agency 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.

If the qualified home infusion therapy supplier is not the same entity as the home health agency furnishing the home health services, the home health agency would continue to bill under the HH PPS on the home health claim, and the qualified home infusion therapy supplier would bill for the services related to the administration of the home infusion drugs on the home infusion therapy services claim.

320.5 - Plan of Care Requirements
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

In accordance with section 1861(iii)(1)(B) of the Act, the beneficiary must be under a plan of care, established by a physician (defined at section 1861(r)(1) of the Act as a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action), prescribing the type, amount, and duration of infusion therapy services that are to be furnished, and periodically reviewed, in coordination with the furnishing of home infusion drugs under Part B.

The qualified home infusion therapy supplier must ensure that all patients are under the care of an applicable provider and have a physician-established plan of care that meets all of the following requirements:

A. *Plan of Care Content - The plan of care must prescribe the type, amount, and duration of the home infusion therapy services 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.*

320.5.1 - Notification of Available Infusion Therapy Options
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

Section 1834(u)(6) of the Act 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 options available (such as home, physician's office, hospital outpatient department) for the furnishing of infusion therapy. Physicians are expected to routinely discuss these infusion therapy options with their patients and annotate these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care.

320.5.2 - Plan of Care Periodic Review and Provider Coordination
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

Depending on patient acuity or the complexity of the drug administration, certain infusions may require more training and education, especially those that require special handling or pre-or post-infusion protocols. The home infusion process typically requires coordination among multiple entities, including patients, physicians, hospital discharge planners, health plans, home infusion pharmacies, and, if applicable, home health agencies.

For payment purposes, all services billed to Medicare by the qualified home infusion therapy supplier must be reflected in the plan of care, which is required to be established and reviewed by the physician. Section 1861(iii)(1)(B) of the Act requires that the plan of care be established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs. This means that the plan of care must be established and reviewed by a physician in consultation with the suppliers responsible for furnishing the home infusion drug and related services. "The statute does not specify that the home infusion plan of care must be established by the same physician who orders the DME and infusion drugs and signs the detailed written order. It is expected that in most cases the physician ordering the home infusion therapy services is the same physician ordering the DME and the infusion drug, however, this may not always be the case. Furthermore, if a hospital-based physician initially orders the infusion drug and/or the home infusion therapy services for a patient, they will likely not continue to follow the patient after discharge; however, in order for the patient to continue to receive home infusion therapy services, that patient must be under a physician-established plan of care that is reviewed periodically. Any updates to this plan of care would not likely be made by the hospital-based physician, rather by whichever physician that takes over the patient's care after hospital discharge. In this case, a physician serving as the "applicable provider" as described in section 320.4 could also be the "ordering physician" as mentioned in section 320.5. Regardless of whether the physician ordering the home infusion drug is the same physician ordering and updating the home infusion therapy services, there must be care coordination among all entities in order to meet the plan of care requirements."

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. The DME supplier is also required to consult with the physician prescribing the infusion drug as needed to confirm the drug order and any necessary changes, refinements, or additional evaluation to the prescribed equipment item(s), and/or service(s).

The plan of care plays an integral part in care coordination between providers, particularly when the physician ordering the home infusion drug is not the same physician establishing the home infusion therapy services plan of care. Coordination between the physician ordering the home infusion drug, the physician

establishing the plan of care for the home infusion therapy services, and the DME supplier furnishing the home infusion drug is imperative in providing safe and effective home infusion therapy. Coordination would likely include review of the patient assessment and evaluation, including interpretation of lab results as they pertain to changes in medication type, dose, or frequency. A current home infusion therapy services plan of care is essential in order to ensure that the qualified home infusion therapy supplier is providing the appropriate professional services, including patient monitoring, to ensure that medication administration is safe and effective.

As coordination is required between the DME supplier responsible for furnishing the infusion drug, and both the physician establishing the home infusion therapy services plan of care and the prescriber of the home infusion drug, all entities are expected to be involved in this care coordination process.

320.6 - Professional Services, Including Nursing Services, for Home Infusion Therapy
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

In order to ensure that patients have access to expert clinical knowledge and advice to safely and effectively manage all aspects of treatment, especially in the event of an urgent or emergent infusion-related situation, 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:

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.*

Professional services, including nursing services, are skilled services which may be necessary for an individual patient or particular therapy or course of treatment, as determined by the physician responsible for the plan of care. The skilled services provided on an infusion drug administration calendar 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. Additionally, the skilled professional must only furnish services within the scope of his/her practice.

No payment may be made under Medicare Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

The services provided under the home infusion therapy services benefit are distinct from those required and paid under the DME benefit and may include, but are not limited to, the following:

- *Training and education on care and maintenance of vascular access devices:*
    - *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*
- *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*
- *Remote monitoring services*
- *Monitoring services:*
    - *Communicate with patient regarding changes in condition and treatment plan*
    - *Monitor patient response to therapy*
    - *Assess compliance*

Some of these services are further described in sections 320.6.1 and 320.6.2 of this chapter.

320.6.1 - Home Infusion Therapy Services Training and Education
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

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. This is a best practice, as home infusion therapy may entail the use of equipment and supplies with which patients' may not be comfortable or familiar.

Hygiene Training and Maintenance of Vascular Access Devices

Many beneficiaries receiving home infusion therapy may have a unique need for a central vascular access device (CVAD) that requires training and education regarding maintenance and hygiene. This may include education regarding properly disinfecting access points and connectors, dressing changes, and recommended actions in the event of a dislodgement, occlusion, and signs of infection. This also includes teaching the patient about flushing the CVAD after the infusion to ensure all of the medication has been flushed through the tubing and catheter, and locking the catheter to prevent blood from backing into the catheter and clotting. Education regarding specific techniques and solutions (saline or heparin) may also be given to minimize catheter occlusion.

Medication and Disease Management

The qualified home infusion therapy supplier is responsible for ensuring the patient has been properly educated about his/her disease, medication therapy, and lifestyle changes. This could include self-monitoring instruction (nutrition, temperature, blood pressure, heart rate, daily weight, abdominal girth measurement, edema, urine output) and identification of complications or problems necessitating a patient call to the designated infusion clinician (nurse, pharmacist, or physician), or emergency protocols if they arise. The qualified home infusion therapy supplier should ensure the patient's proper understanding of the medication therapy including: drug, route of administration, prescription (dosage, how often to administer, and duration of therapy), side effects and interactions with other medications, adverse reactions to therapy, goals of therapy and indications of progress. Lifestyle education regarding behavior and food/fluid modifications/restrictions, symptom management, and infection control are also important aspects of patient education.

While the durable medical equipment supplier is responsible for training the patient and caregiver on the infusion pump operation, maintenance, and troubleshooting, the qualified home infusion therapy supplier would be responsible for all other aspects of medication administration. These services may include inspection of medications, containers, and supplies prior to use; proper drug storage and disposal; hand hygiene and aseptic technique; education on pre/post medication/hydration administration; and training on medication preparation. Household precautions for chemotherapy drugs including spills, handling body wastes, and physical contact precautions must also be addressed.

Patient Assessment and Evaluation

Comprehensive patient assessment is imperative when providing home infusion therapy. The home infusion therapy supplier may evaluate patient history, current physical and mental status, lab reports, cognitive and psychosocial status, family/care-partner support, prescribed treatment, concurrent oral prescriptions, and over-the-counter medications. For patients receiving potentially life-long, continuous intravenous infusion therapy, home infusion therapy suppliers can provide extensive support and education and address necessary lifestyle changes and realistic expectations of life with an ambulatory pump.

320.6.2 - Remote Monitoring and Monitoring Services
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

Qualified home infusion therapy suppliers are required to ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis. Monitoring the patient receiving infusion therapy in their home is an important standard of practice that is an integral part of providing medical care to patients in their home. The expectation is that home infusion therapy suppliers would provide ongoing patient monitoring and continual reassessment of the patient to evaluate response to treatment, drug complications, adverse reactions, and patient compliance.

The plan of care would indicate the need for routine monitoring and specify the interval for evaluation and documentation of patient-reported response to therapy, any adverse effects or infusion complications, verify pump rate, obtain blood work, and obtain any necessary vital signs. Direct communication and coordination with the patient, caregivers, and clinicians regarding any change in the patient's condition is on-going so that any adjustment to treatment is made as needed and in a timely fashion. This can be done remotely or directly during in-home patient visits at specified intervals.

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.

Qualified home infusion therapy suppliers may use all available remote monitoring methods that are safe and appropriate for their patients and clinicians and as specified in the plan of care as long as adequate security and privacy protections are utilized.

320.7 - Home Infusion Therapy Drugs
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

"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 and 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. See section 50.2 of this chapter for instructions regarding the determination of self-administered drugs or biologicals.

See the Medicare Claims Processing Manual, Chapter 32, Section 411 for a list of drugs and biologicals that meet the criteria of a home infusion drug. It is important to note that this list is not static.

The home infusion drugs identified for coverage of home infusion therapy services are paid under the DME benefit. The related pharmacy services, furnished by a Medicare enrolled DMEPOS supplier, including the preparation and dispensing of home infusion drugs, are also paid under the DME benefit and are not part of this specific home infusion therapy services benefit.

320.7.1 - Determining Qualifying Home Infusion Drugs
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

In general, Medicare Part B covers a limited number of home infusion drugs through the DME benefit if:

1. *the drug is necessary for the effective use of an infusion pump classified as DME and determined to be reasonable and necessary for administration of the drug; and*
2. *the drug being used with the pump is itself reasonable and necessary for the treatment of an illness or injury.*

Specifically, under this home infusion therapy services benefit, a home infusion drug must require infusion through an external infusion pump that is covered under the DME benefit. If the drug or biological can be infused through a disposable pump or by a gravity drip, it does not meet this criterion.

Only certain types of infusion pumps are covered under the DME benefit. The Medicare National Coverage Determinations Manual, Publication 100-03, Chapter 1, Section 280.1 describes the types of infusion pumps that are covered under the DME benefit. The DME MACs then specify the details of which infusion drugs are covered with these pumps.

The drugs and biologicals identified in the DME Local Coverage Determination (LCD) for External Infusion Pumps (L33794) qualify as home infusion drugs as long as they are infused intravenously or subcutaneously over a period of 15 minutes or more, are not classified as insulin for insulin pump use, and are not on a self-administered drug exclusion list. These drugs continue to be paid for under the DME benefit as supply drugs to the covered infusion pump. Any additional training and education services needed for the patient to administer these drugs at home would be covered under this home infusion therapy services benefit.

There are other infusion drugs covered under Part B that could potentially be added to the DME LCD for External Infusion Pumps (L33794) and thus qualify for services under the home infusion therapy services benefit. Allowing the DME MACs to maintain the list of infusion drugs and biologicals ensures quarterly review of any and all medications that meet the criteria for external infusion pumps, thus ensuring an up to date, inclusive benefit.

320.8 - Payment for Home Infusion Therapy Services
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

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. The single payment amount represents payment in full for all costs associated with the furnishing of home infusion therapy services.

320.8.1 - Home Infusion Drug Payment Categories
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

Payment for home infusion therapy services is contingent upon a corresponding home infusion drug being covered and paid for under the DME benefit. Therefore, home infusion therapy suppliers must ensure that the appropriate drug is billed by the DME supplier no more than 30 days prior to the home infusion therapy service visit.

Home infusion drugs are assigned to three payment categories, as determined by the HCPCS J-code:

- ***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 chemotherapy infusions, including certain chemotherapy drugs, and other highly complex drugs and biologicals.*

Specific billing codes are associated with each of the three payment categories in order for qualified home infusion therapy suppliers to bill Medicare for home infusion therapy services on an infusion drug administration calendar day.

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.

The J-codes for eligible home infusion drugs, the G-codes for the home infusion therapy services, and billing instructions for home infusion therapy payments are found in the Medicare Claims Processing Manual Chapter 32, Section 411.

320.8.2 - Infusion Drug Administration Calendar Day and Unit of Single Payment
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

Section 1834(u)(7)(E)(i) of the Act states that payment to a qualified home infusion therapy supplier for an "infusion drug administration calendar day" in the individual's home refers to payment only for the date on which professional services, as described in section 1861(iii)(2)(A) of the Act, were furnished to administer such drugs to such individual. This means the day on which home infusion therapy services are furnished by a skilled professional in the individual's home on the day of infusion drug administration. This includes all such drugs administered to such individual on such day.

A "single payment amount" for an infusion drug administration calendar day means that all home infusion therapy services, which include professional services, including nursing; training and education; remote monitoring; and monitoring, are built into the day on which the services are furnished in the home and the drug is being administered. There may be professional services furnished in the patient's home that do not occur on a day the drug is being administered, however, the home infusion therapy services payment is a unit of single payment. In other words, payment for an infusion drug administration calendar day is a bundled payment amount per visit in the patient's home furnishing services specifically related to the physical process by which the drug enters the patient's body. The home infusion therapy payment rates reflect the increased complexity of the skilled professional services provided per payment category. 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.

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. Although the single payment covers both professional services under section 1861(iii)(2)(A) and training and education, remote monitoring, and other monitoring services under section 1861(iii)(2)(B), payment is only issued on days on which professional services are provided in the patient's home, by the qualified home infusion therapy supplier.

The qualified home infusion therapy supplier must submit, in line-item detail on the claim, an appropriate G-code for each infusion drug administration calendar day. The claim should include the length of time, in 15-minute increments, for which professional services were furnished. Billing instructions for home infusion therapy services are found in the Medicare Claims Processing Manual Chapter 32 Section 411.

320.8.3 - Initial Visits and Subsequent Visits for Home Infusion Therapy Services
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

The first visit furnished by a qualified home infusion therapy supplier to furnish services in the patient's home may be longer or more resource intensive than subsequent visits. For each of the three payment categories listed in 320.8.1 of this chapter, 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.

If a patient receiving home infusion therapy services is discharged from such services, in order to bill a first visit again, the patient's history must show a gap of more than 60 days between home infusion therapy service visits. This means that upon re-admission, there cannot be a G-code billed for this patient within the past 60 days, and the last G-code billed for this patient must show that the patient had been discharged. A qualified home infusion therapy supplier could bill the first visit payment amount on day 61 for a patient who had previously been discharged from service.

The G-codes for the initial and subsequent home infusion therapy service visits, and instructions for billing for home infusion therapy services payments are found in the Medicare Claims Processing Manual Chapter 32 Section 411.

320.9 - Medical Review
(Rev. 10463, Issued: 11-13-20, Effective: 01-01-21, Implementation: 01-04-21)

All payments under this benefit may be subject to a medical review adjustment reflecting the following:

1. *Beneficiary eligibility.*
2. *Plan of care requirements.*
3. *Medical necessity determinations.*