CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 11103	**Date: November 10, 2021**
	Change Request 12508

SUBJECT: Clarifying Instructions for Billing and Processing and Payment of Claims Based on Locality of the Home Infusion Therapy (HIT) Service Visit

I. SUMMARY OF CHANGES: This Change Request (CR) provides the Medicare contractors with clarifying instructions for billing and processing of claims based on the locality of the Home Infusion Therapy (HIT) service visit. This change request applies to chapter 32, section 411.

EFFECTIVE DATE: January 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 4, 2022

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/A	

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:
One Time Notification

Attachment - One-Time Notification

Pub. 100-20	Transmittal: 11103	Date: November 10, 2021	Change Request: 12508

SUBJECT: Clarifying Instructions for Billing and Processing and Payment of Claims Based on Locality of the Home Infusion Therapy (HIT) Service Visit

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I. GENERAL INFORMATION

A. Background: Section 5012(d) of the 21st Century Cures Act (Pub. L 144-255) amended sections 1861(s)(2) and 1861(iii) of the Social Security Act (the Act), requiring the Secretary to establish a new Medicare home infusion therapy services benefit. The Medicare Home Infusion Therapy (HIT) 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 therapy services and home infusion drugs furnished by a qualified home infusion therapy supplier.

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.

Section 1834(u)(1)(A)(ii) of the Act states that a unit of single payment under this payment system is for each infusion drug administration calendar day in the individual's home, and requires the Secretary, as appropriate, to establish single payment amounts for different types of infusion therapy, considering unit variation in utilization of nursing services by therapy type.

Section 1834(u)(1)(A)(iii) of the Act provides a limitation to the single payment amount, requiring that it shall not exceed the amount determined under the physician fee schedule (under section 1848 of the Act) for infusion therapy services furnished in a calendar day if furnished in a physician office setting.

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted to reflect a geographic wage index and other costs that may vary by region. Subparagraphs (A) and (B) of section 1834(u)(3) of the Act specify annual adjustments to the single payment amount that are required to be made beginning January 1, 2022. In accordance with these sections, the single payment amount will increase by the percent increase in the Consumer Price Index (CPI) for all urban consumers (CPI-U) for the 12-month period ending with June of the preceding year, reduced by the 10 year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP).

Section 1834(u)(1)(C) of the Act allows the Secretary discretion to adjust the single payment amount to reflect outlier situations and other factors as the Secretary determines appropriate, in a budget neutral manner.

B. Policy: As described in the 21st Century Cures Act, a separate payment for home infusion therapy services will be made under the permanent home infusion therapy benefit to qualified home infusion suppliers, effective January 1, 2021. Home infusion drugs are assigned to three payment categories, as determined by the Healthcare Common Procedure Coding System (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. The Centers for Medicare & Medicaid Services (CMS) will continue to use the G-codes for the professional services furnished on an infusion drug administration calendar day for each payment category.

In accordance with Section 1834(u)(1)(A), the payment amount of each G-code for each of the three categories for professional services furnished for is based on only one single unit of payment per drug category 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.

While the qualified HIT supplier should submit claims for the appropriate G-code in multiple units of 15-minute increments to report the actual duration of each HIT service visit, the payment must be equal to only one single G-code unit per visit. See Attachment A in Change Request (CR) 11880 for detailed descriptions of the Home Infusion Therapy Service G-codes, the Time Increments table for reporting multiple units per G-code, the Payment Categories for Home Infusion Therapy Professional Services, and the Payment Categories for Home Infusion Drugs.

In accordance with section 1834(u)(1)(B) of the Act, we are using the Geographic Adjustment Factor (GAF) to wage adjust the home infusion therapy services payment based on locality. The qualified home infusion therapy supplier will submit all home infusion therapy service claims on the 837P/CMS-1500 professional and supplier claims form to the A/B Medicare Administrative Contractors (MACs). The A/B MAC must allow any home infusion therapy supplier enrolled with them to submit claims for services rendered in locations within or outside their normal processing jurisdiction. The A/B MAC must process and pay for the home infusion therapy service claim based on where the service was rendered (Item 32 of the CMS-1500 or the Electronic Equivalent Loop 2310C, Segment NM1 Service Facility Location information), including possible localities within and outside of the A/B MAC's normal processing jurisdiction.

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	
12508.1	Effective for claims with a Date of Service on or after January 1, 2021, the contractor shall make necessary systems changes to allow all MACs to process and pay for home infusion therapy service claims rendered within and outside of their normal processing jurisdiction based on where the service was rendered (Item 32 of the CMS-1500 or the Electronic Equivalent Loop 2310C, Segment NM1 Service Facility Location information). Note: Pricing locality should be based on where the service was rendered rather than the beneficiaries' address on MAC files.						X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12508.1.1	The contractor shall map a pricing locality code starting with an alpha character to the Common Working File (CWF) HUBC transmission record in order to bypass CWF error 74x1.						X			
12508.2	The contractor shall use the CMS zip+4 file to pay based on locality.						X			
12508.3	Contractors shall allow any qualified home infusion therapy supplier enrolled with them to submit claims for services provided within or outside of the MAC's normal processing jurisdiction.		X							
12508.4	Contractors shall not adjust previously processed claims unless brought to their attention.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	Change Requests 11880, 12108, and 12324

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

V. CONTACTS

Pre-Implementation Contact(s): Cheryl Gilbreath, cheryl.gilbreath@cms.hhs.gov (Benefit Policy) , Yvette Cousar, yvette.cousar@cms.hhs.gov (Claims Processing)

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 0