CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10621	**Date: March 15, 2021**
	Change Request 12108

SUBJECT: Updated Billing Requirements for Home Infusion Therapy (HIT) Services on or After January 1, 2021

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to provide contractor guidance and claims processing systems instructions necessary to implement new changes for HIT 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: July 6, 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
R	32/411/4//Billing and Payment Requirement
R	32/411/5 /Return as Un-Processable, Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages
R	32/411/6 CWF and MCS Editing Requirements

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. 100-04	Transmittal: 10621	Date: March 15, 2021	Change Request: 12108

SUBJECT: Updated Billing Requirements for Home Infusion Therapy (HIT) Services on or After January 1, 2021

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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 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, taking into account variation in utilization of nursing services by therapy type.

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. CMS has established a single payment amount for each of the three categories for professional services furnished for each infusion drug administration calendar day.

In the event that multiple drugs, which are not all assigned to the same payment category, are administered on the same infusion drug administration calendar day, a single payment would be made that is equal to the highest payment category.

Because the home infusion therapy services are contingent upon a home infusion drug J-code being billed, the appropriate drug associated with the visit must be billed no more than 30 days prior to the visit. Suppliers must ensure that the appropriate drug associated with the visit is billed with no more than 30 days prior to the visit.

Attachment A in Change Request 11880 lists the home infusion therapy service G-codes and corresponding home infusion therapy drug J-codes.

Effective for services on or after January 1, 2021, the payment category may be determined by the contractor for any new home infusion drug additions to the Local Coverage Determination (LCD) for External Infusion Pumps as

identified by the following Not-Otherwise-Classified (NOC) codes:

- J7799 - Not otherwise classified drugs, other than inhalation drugs, administered through DME
- J7999 - Compounded drug, not otherwise classified.

When either one of these NOC codes id used for a home infusion drug, the home infusion therapy supplier must identify the name of the drug in the comment section (data element 2400/SV101-7 of the 837P or Item 19 of the CMS-1500) of the professional service claim for the corresponding home infusion therapy service G-code.

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	
12108.1	Effective for claims with a Date of Service on or after January 1, 2021, CWF shall create a new reject claim when a Part B Professional claim with one of the following six HCPCS 'G0068', 'G0069' 'G0070', 'G0088', 'G0089', or 'G0090' and DME claim in history with one of the following not otherwise classified J-codes (J7799 or J7999) within 30 days prior to the incoming Date of Service.								X	
12108.1.1	CWF will allow override of the new reject in the detail line.								X	
12108.2	Contractors shall suspend Part B claims with G codes when there is a DME claim reporting J7799 or J7999. Contractors shall search the Part B claim to make sure the drug name is indicated in item 19 or the 1500 claim or EMC equivalent.		X							
12108.2.1	Contractors shall override the CWF reject if the home infusion therapy drug name is identified on the claim.		X							
12108.3	Contractors shall deny CWF rejected claims and use the following messages if a drug is not identified, or the identified drug is not listed as a home infusion drug: CARC16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Information REF), if present. RARC N350 - Missing/incomplete/invalid description of service for a Not Otherwise Classified (NOC) code or for an Unlisted/By Report procedure. MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente. Group Code CO									
12108.4	For edits established with CR 10836 contractors shall allow override capability at the claim detail line when the NOC drug codes (J7799 or J7999) are used for claims with dates of service January 1, 2019 through December 31, 2020.				X					
12108.5	Contractors shall not search or adjust claims prior to the issuance of this instruction unless brought to their attention.		X		X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12108.6	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:

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	Change Request 11880 and Change Request 10836

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 , Cheryl Gilbreath, 410-786-5919 or cheryl.gilbreath@cms.hhs.gov

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 Claims Processing Manual
Chapter 32 – Billing Requirements for Special Services

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(Rev. 10621; Issued: 03-15-21)

411.4- Billing and Payment Requirements

(Rev. 10621, Issued: 03-15-21, Effective: 01-01-21, Implementation: 07-06-21)

Contractors shall accept and pay for home infusion therapy services to eligible home infusion therapy suppliers (new specialty **D6**) effective for claim lines with dates of service on or after January 1, 2021 using the one of the following 'G' codes and applicable 'J' codes listed in section 411.3 of this chapter. Claims for the home infusion therapy service G-codes are billed to the A/B MACs and are payable to home infusion therapy suppliers; this service is no longer payable to DME suppliers. The applicable 'J' codes are billed to the DME MACs by the DME supplier.

Contractors shall use Type of Service (TOS) Code 1 for all six G-codes. Contractors shall pay only one of the G-codes per line item date of service when one of the drugs from the applicable category is billed with the same line item date of service or a date of service within 30 days prior to the G-code visit.

NOTE:

- The fees associated with the G-codes on the MPFSD fee file will be "a per day rate;" therefore, the units on the line should not be multiplied by the rate.
  The drug remains separately payable from the G-code line item

Home infusion therapy suppliers will report the following HCPCS G-codes associated with the payment categories for the professional services furnished in the individual's home and on an infusion drug administration calendar day.

Contractors shall suspend Part B claims with G codes when there is a DME claim reporting J7799 or J7999. Contractors shall search the Part B claim to make sure the drug name is indicated in item 19 or the 1500 claim or EMC equivalent. Contractors shall override the CWF reject if the home infusion therapy drug name is identified on the claim.

If the drug name is not identified, Contractors shall deny CWF rejected claims and use the messages in 411.5

Because the home infusion therapy services are contingent upon a home infusion drug J-code, home infusion therapy suppliers must ensure that the appropriate drug associated with the visit is billed no more than 30 days prior to the visit. In the event that multiple visits occur on the same date of service, or multiple drugs, which are not all assigned to the same payment category, are administered on the same infusion drug administration calendar day, a single payment would be made that is equal to the highest payment category. Suppliers must only bill for one visit and should report the highest paying visit with the applicable drug.

To differentiate the first visit from all subsequent visits, home infusion therapy suppliers may only bill one of the "initial visit" G-codes to indicate an visit for a new patient who had previously received their last home infusion therapy service visit more than 60 days prior to the new initial home infusion therapy service visit.

Home infusion therapy suppliers should report visit length in 15-minute increments (15 minutes=1 unit). See the Table 1 below for the rounding of units.

Table 1: Time Increments

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

Table 2 shows the use of the G-codes established for the home infusion therapy benefit, and reflects the therapy type and complexity of the drug administration.

Table 2: Payment Categories for Home Infusion Therapy Professional Services (G-Codes)

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

- **G0068:** Professional services for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes

  Short Descriptor: Adm IV infusion drug in home

- **G0069:** Professional services for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes

  Short Descriptor: Adm SQ infusion drug in home

- **G0070:** Professional services for the administration of intravenous chemotherapy or other intravenous highly complex drug or biological infusion for each infusion drug administration calendar day in the individual's home, each 15 minutes.

  Short Descriptor: Adm of IV chemo drug in home

- **G0088:** Professional services, initial visit, for the administration of anti-infective, pain management, chelation, pulmonary hypertension, inotropic, or other intravenous infusion drug or biological (excluding chemotherapy or other highly complex drug or biological) for each infusion drug administration calendar day in the individual's home, each 15 minutes.

Short Descriptor: Adm IV drug 1st home visit

- **G0089:** Professional services, initial visit, for the administration of subcutaneous immunotherapy or other subcutaneous infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes.

  Short Descriptor: Adm SubQ drug 1st home visit

- **G0090:** Professional services, initial visit, for the administration of intravenous chemotherapy or other highly complex infusion drug or biological for each infusion drug administration calendar day in the individual's home, each 15 minutes.

  Short Descriptor: Adm IV chemo 1st home visit

411.5 – Claim Adjustment Reason Codes, Remittance Advice Remark Codes, Group Codes, and Medicare Summary Notice Messages

(Rev. 10621, Issued: 03-15-21, Effective: 01-01-21, Implementation: 07-06-21)

Contractors shall deny the CWF rejected claim if a new G-code is received for the same date of service as a previous claim was paid for the same line item date of service.

NOTE: The provider should submit an adjustment to the original claim to receive the higher payment.

Contractors shall use the following CARC/RARC codes when denying claims:

CARC 97 - The benefit for this service is included in the payment/allowance for another service/procedure that has already been adjudicated. Usage: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N111 - No appeal right except duplicate claim/service issue. This service was included in a claim that has been previously billed and adjudicated.

Claim Adjustment Group Code - CO (Contractual Obligation)

MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.

Contractors shall deny the CWF rejected G-code line when the claim has recycled three times without finding the associated drug J-code claim and use the following messages:

CARC 16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N657 - This should be billed with the appropriate code for these services. Claim Adjustment Group Code - CO (Contractual Obligation)

MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.

Contractors shall deny CWF rejected claims for more than one claim line service of G0088, G0089, or G0090 within a 60 day period and use the following messages:

CARC 96 - Non-covered charge(s). At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason [sic] Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N640 - Exceeds number/frequency approved/allowed within time

period. Group Code - CO (Contractual Obligation)

Contractors shall deny claims for J7799 or J7999 that do not contain the drug name in item 19 the claim and use the following messages:

CARC16 - Claim/service lacks information or has submission/billing error(s). Usage: Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N350 - Missing/incomplete/invalid description of service for a Not Otherwise Classified (NOC) code or for an Unlisted/By Report procedure.

MSN message: 41.14: This service/item was billed incorrectly. 41.14- Este servicio o artículo fue facturado incorrectamente.

Group Code CO

411.6 – CWF and MCS Editing Requirements

(Rev. 10621, Issued: 03-15-21, Effective: 01-01-21, Implementation: 07-06-21)

MCS shall create a new edit to identify when there is more than one of the following six HCPCS ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ with Date of Service on or after 1/1/2021 for the same Date of Service on the same Part B Professional claim.

CWF shall create a new reject for a Part B Professional claim with one of the following six HCPCS codes ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ with Date of Service on or after 1/1/2021 and there is no DME claim in history with one of the identified J-codes within 30 days prior to the incoming Date of Service.

NOTE: This edit shall have override capability at the claim detail line

CWF and contractors shall recycle ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ claim up to three times for a total of 15 days until a claim containing an allowable drug J-code from above is received with the same line item date of service or within 30 days prior to the line item date of service of the G-code.

CWF shall create a new reject for a Part B Professional claim with one of the following six ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes with a Date of Service on or after 1/1/2021 when there is a Part B claim in history with one of the identified six ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes for the same Date of Service.

NOTE: This edit shall have override capability at the claim detail line

CWF shall create a new reject for a Part B Professional claim with one of the new ‘G0088’, ‘G0089’, or ‘G0090’ codes and in history is an allowed DME or Part B Professional claim with any of the six ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes and the Dates of Service is within 60 days prior to the incoming claim’s Dates of Service. The incoming claim has Dates of Service on or after 1/1/2021.

CWF should still subject an incoming Part B Professional claim to the edit if it is within 60 days of posted DME claim, and if the claim in history is DME and has one of the three existing ‘G0068’, ‘G0069’ ‘G0070’ codes and has Dates of Service prior to 1/1/2021.

CWF shall create a new Informational Unsolicited Response (IUR) when a Part B Professional claim or a DME claim with one of the six ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ codes is received and in history is a Part B Professional claim with one of the three new ‘G0088’, ‘G0089’, or ‘G0090’ codes with Dates of Service within 60 days after the incoming claim’s Dates of Service.

CWF shall ensure that all new edits and the IUR appear on the ORPN Report.

CWF shall create a new reject claim when a Part B Professional claim with one of the following six HCPCS ‘G0068’, ‘G0069’ ‘G0070’, ‘G0088’, ‘G0089’, or ‘G0090’ and DME claim in history with one of the following not otherwise classified J-codes (J7799 or J7999) within 30 days prior to the incoming Date of Service.

CWF will allow the override of the new reject in the detail line.