

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11219	Date: January 27, 2022
	Change Request 12545

SUBJECT: Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs and New Modifier for Audio-only Services

I. SUMMARY OF CHANGES: This Change Request (CR) revises the Medicare Benefit Policy Manual, Chapter 17, and the Medicare Claims Processing Manual, Chapter 39, to reflect changes made in the CY 2022 Physician Fee Schedule Final Rule.

EFFECTIVE DATE: January 1, 2022

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: March 1, 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
R	39/30.5/Site of service (telecommunications)
R	39/30.6/Coding
R	39/30.6.1/Adjustments to the Bundled Payment Rate
R	39/30.8/Locality Adjustments

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

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SUBJECT: Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs and New Modifier for Audio-only Services

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I. GENERAL INFORMATION

A. Background: Section 2005 of the SUPPORT for Patients and Communities Act established a new Medicare Part B benefit for Opioid Treatment Programs (OTPs). CMS finalized policies related to implementing this new benefit in the Calendar Year (CY) 2020 Physician Fee Schedule final rule. CMS finalized additional OTP policies in the CY 2022 Physician Fee Schedule final rule.

In the CY 2020 PFS final rule (84 FR 62645 and 62646), CMS finalized allowing the use of two-way interactive audio/ video communication technology, as clinically appropriate, to furnish the counseling and therapy portions of the weekly bundle of services and additional counseling or therapy services furnished by OTPs.

In the March 31, 2020 COVID-19 IFC therapy and counseling portions of the weekly bundles, and any additional counseling or therapy, can be furnished using audio-only telephone calls rather than via two-way interactive audio/ video communication technology for the duration of the PHE for COVID-19.

B. Policy: Real-Time Interactive Audio-Only Telecommunications System

Effective January 1, 2022, as stated under § 410.67(b)(3) and (4), OTPs can furnish individual and group therapy and substance use counseling using audio-only telephone calls rather than two-way interactive audio/video communication technology after the conclusion of the PHE for COVID-19 in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met.

CMS interprets the requirement that audio/video technology is “not available to the beneficiary” to include circumstances in which the beneficiary is not capable of or has not consented to the use of devices that permit a two-way, audio/video interaction because in each of these instances audio/video communication technology is not able to be used in furnishing services to the beneficiary.

After the conclusion of the PHE for COVID-19, CMS finalized its proposal that service-level modifier FQ (Audio-only service) be appended to claims submitted for the counseling and therapy add-on code (HCPCS code G2080) when services are furnished via an audio-only interaction. The use of this modifier certifies that the practitioner had the capacity to furnish the services using two-way, audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary.

Real-Time Interactive Audio and Video Telecommunications System

After the conclusion of the PHE for COVID-19, when two-way interactive audio/video communication technology is used to furnish additional counseling and therapy services billed under the counseling and therapy add-on code (HCPCS code G2080), OTPs will be required to append modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System)

to the claim.

Note: After the conclusion of the PHE for COVID-19, when OTPs report HCPCS code G2080 on the claim without modifier 95 and without modifier FQ, this indicates that the additional counseling and therapy services was furnished in-person.

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	
12545 - 04.1	Medicare contractors shall be aware of changes to the Medicare Claims Processing Manual contained in this change request.	X	X							
12545 - 04.2	Effective for claims with dates of service on and after January 1, 2022, contractors shall accept claims for Opioid Treatment Program services with new informational HCPCS modifier FQ (Audio-only service), to be used to identify that the service was furnished using audio-only communication technology.	X	X							
12545 - 04.3	Effective for claims with dates of service on and after January 1, 2022, contractors shall accept claims for Opioid Treatment Program services with modifier 95 (synchronous telemedicine service rendered via a real-time audio and video telecommunications system), to be used to identify that the service was furnished using audio-video communication technology.	X	X							
12545 - 04.4	Effective for claims with dates of service on and after January 1, 2022, contractors shall accept claims for new HCPCS codes G1028 (Take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid	X	X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Treatment Program); List separately in addition to code for primary procedure.) billed by Opioid Treatment Programs.									
12545 - 04.4.1	A/B MACs shall not apply beneficiary coinsurance for HCPCS code G1028. The Medicare Part B deductible shall apply.		X							
12545 - 04.4.2	A/B MACs shall include HCPCS codes G1028 in any editing that is applied to HCPCS codes G2067-G2080, G2215, and G2216 regarding provider specialty code for OTPs (D5) and Place of Service code 58.		X							
12545 - 04.4.3	A/B MACs shall update PARM PRMOTPHP with HCPCS G1028. The Part A MACs are responsible.	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: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
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Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Lindsey Baldwin, 410-786-1694 or lindsey.baldwin@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 39 – Opioid Treatment Programs (OTPs)

Table of Contents

(Rev. 11219; Issued: 01-27-22)

30.5 - Site of service (telecommunications)

(Rev. 11219; Issued: 01-27-22; Effective: 01-01-22; Implementation: 03-01-22)

OTPs can use two-way interactive audio-video communication technology, as clinically appropriate, to furnish the substance use counseling and individual and group therapy services included in the bundled payment, as well as the add-on code for additional counseling and therapy. Additionally, beginning January 1, 2021, OTPs can use two-way interactive audio-video communication technology, as clinically appropriate, to furnish the periodic assessment add-on code. During the Public Health Emergency (PHE) for the COVID-19 pandemic, *as well as after the conclusion of the PHE*, the therapy and counseling portions of the weekly bundles of services furnished by OTPs, as well as any additional counseling or therapy payable under the add-on code for additional counseling or therapy, may be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID-19 pandemic if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met.

Additionally, during the PHE, as defined in 42 CFR 400.200, periodic assessments may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements, and in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls during the PHE if all other applicable requirements are met.

After the conclusion of the PHE for the COVID-19 pandemic, CMS expects OTPs to add Modifier FQ (The service was provided using audio-only communication technology) to the claim for counseling and therapy provided via audio-only telecommunications using HCPCS code G2080. Additionally, after the conclusion of the PHE for the COVID-19 pandemic, CMS expects OTPs to add Modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) to the claim for counseling and therapy provided via audio-video telecommunications using HCPCS code G2080.

As OTP services are not PFS services, no originating site facility fee (HCPCS code Q3014) applies to OUD treatment services, and OTPs are not authorized to bill for the originating site facility fee. Additionally, the payment for the substance use counseling and individual and group therapy are included in the bundled payment

rates made to OTPs; therefore, the practitioner furnishing the service remotely should not bill separately for the service.

30.6 – Coding

(Rev. 11219; Issued: 01-27-22; Effective: 01-01-22; Implementation: 03-01-22)

The codes describing bundled payments made to OTPs are HCPCS codes G2067-G2075. There are add-on codes described by HCPCS codes G2076-G2080, HCPCS codes G2215, G2216, *and G1028*. Only an entity enrolled with Medicare as an OTP can bill these codes. Additionally, OTPs are limited to billing only these codes describing bundled payments, and may not bill for other codes, such as those paid under the PFS.

The coding structure for OUD treatment services varies by the medication administered. There are G codes for weekly bundles describing treatment with methadone, oral buprenorphine, injectable buprenorphine, buprenorphine implants (insertion, removal, and insertion/removal), extended-release injectable naltrexone, a non-drug bundle, and one for a medication not otherwise specified (see full list of codes below).

The code describing the bundled payment for an episode of care with a medication not otherwise specified (HCPCS code G2075) should be used when the OTP furnishes MAT with a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD. OTPs may use this code until CMS has the opportunity to propose and finalize a new G code to describe the bundled payment for treatment using that drug and price it accordingly in the next rulemaking cycle.

HCPCS code G2075 should not be used when the drug being administered is not a new opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD, and therefore, for which Medicare would not have the authority to make payment since section 1861(jjj)(1)(A) of the Act requires that the medication must be an opioid agonist or antagonist treatment medication approved by the FDA under section 505 of the FFDCA for the treatment of OUD.

HCPCS code G2074, which describes a non-drug bundle, can be billed for services furnished during an episode of care when a medication is not administered, but other services in the bundle are furnished. For example, when a patient receives a buprenorphine injection on a monthly basis, the OTP will only require payment for the medication during the first week of the month when the injection is given, and therefore, would bill the code describing the bundle that includes injectable buprenorphine during the first week of the month and would bill the code describing the non-drug bundle for the remaining weeks in that month for services such as substance use counseling, individual and group therapy, and toxicology testing.

NOTE: Some of the bundled payment codes describe a drug that is typically only administered once per month, such as the injectable drugs, or once in a 6-month period, in the case of the buprenorphine implants. In those cases, the code describing the bundled payment that includes the cost of the drug would be billed during the week that the drug is administered, and if at least one service is furnished in a subsequent week, the non-drug bundle would be billed. For example, in the case of a patient receiving injectable buprenorphine, *CMS* would expect that HCPCS code G2069 would be billed for the week during which the injection was administered and that HCPCS code G2074, which describes a bundle not including the drug, would be billed during any subsequent weeks that at least one non-drug service is furnished until the injection is administered again, at which time HCPCS code G2069 would be billed again for that week. *CMS notes* that as HCPCS codes G2067 – G2075 cover episodes of care of 7 contiguous days, *CMS* will not permit an OTP to bill any of these codes for the same beneficiary more than once per 7 contiguous day period. Additionally, consistent with FDA labelling, *CMS does* not generally expect the codes describing bundled payments including the injectable drugs (HCPCS codes G2069 and G2073) to be furnished more than once every 4 weeks. Similarly, consistent with FDA labelling, *CMS does* not generally expect the codes describing bundled payments including insertion of the buprenorphine implants (HCPCS codes G2070 and G2072) to be furnished more than once every 6 months.

CMS understands there are limited clinical scenarios when a beneficiary may be appropriately furnished OUD treatment services at more than one OTP within a 7 contiguous day period, such as for guest dosing or when a beneficiary transfers care between OTPs. In these limited circumstances, each of the involved OTPs may bill the appropriate HCPCS codes that reflect the services furnished to the beneficiary. *CMS expects* that both OTPs involved would provide sufficient documentation in the patient's medical record to reflect the clinical situation and services provided. Additionally, in instances in which a patient is switching from one drug to another, the OTP should only bill for one code describing a weekly bundled payment for that week and should determine which code to bill based on which drug was furnished for the majority of the week.

30.6.1 - Adjustments to Bundled Payment Rate

(Rev. 11219; Issued: 01-27-22; Effective: 01-01-22; Implementation: 03-01-22)

There are add-on codes for intake activities, periodic assessments, take-home supplies of methadone, take home supplies of oral buprenorphine, additional counseling or therapy services furnished, and for take-home supplies of naloxone.

CMS notes that the add-on code describing intake activities (HCPCS code G2076) should only be billed for new patients (that is, patients starting treatment at the OTP).

There are two add-on codes that describe take-home doses of medication, one for take-home supplies of methadone (HCPCS code G2078), which describes up to 7 additional days of medication, and can be billed along with the respective weekly bundled payment in units of up to 3 (for a total of up to a one month supply), and one for take-home supplies of oral buprenorphine (HCPCS code G2079), which also describes up to 7 additional days of medication and can be billed along with the base bundle in units of up to 3 (for a total of up to a 1 month supply). SAMHSA allows a maximum take-home supply of one month of medication; therefore, *CMS does* not expect the add-on codes describing take-home doses of methadone and oral buprenorphine to be billed any more than 3 times in one month (in addition to the weekly bundled payment). The add-on code for take-home doses of methadone can only be used with the methadone weekly episode of care code (HCPCS code G2067). Similarly, the add-on code for take-home doses of oral buprenorphine can only be used with the oral buprenorphine weekly episode of care code (HCPCS code G2068).

HCPCS code G2080 may be billed when counseling or therapy services are furnished that substantially exceed the amount specified in the patient's individualized treatment plan. OTPs are required to document the medical necessity for these services in the patient's medical record.

The codes and long descriptors for the OTP bundled services and add-on services are:

- HCPCS code G2067: Medication assisted treatment, methadone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2068: Medication assisted treatment, buprenorphine (oral); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2069: Medication assisted treatment, buprenorphine (injectable); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2070: Medication assisted treatment, buprenorphine (implant insertion); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2071: Medication assisted treatment, buprenorphine (implant removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2072: Medication assisted treatment, buprenorphine (implant insertion and removal); weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2073: Medication assisted treatment, naltrexone; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).

- HCPCS code G2074: Medication assisted treatment, weekly bundle not including the drug, including substance use counseling, individual and group therapy, and toxicology testing if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2075: Medication assisted treatment, medication not otherwise specified; weekly bundle including dispensing and/or administration, substance use counseling, individual and group therapy, and toxicology testing, if performed (provision of the services by a Medicare-enrolled Opioid Treatment Program).
- HCPCS code G2076: Intake activities, including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho- social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- HCPCS code G2077: Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- HCPCS code G2078: Take-home supply of methadone; up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- HCPCS code G2079: Take-home supply of buprenorphine (oral); up to 7 additional day supply (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- HCPCS code G2080: Each additional 30 minutes of counseling or group or individual therapy in a week of medication assisted treatment, (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- HCPCS code G2215: Take-home supply of nasal naloxone; *2-pack of 4mg per 0.1 mL nasal spray* (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- HCPCS code G2216: Take-home supply of injectable naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- *HCPCS code G1028: Take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*

30.8 - Locality Adjustments

(Rev. 11219; Issued: 01-27-22; Effective: 01-01-22; Implementation: 03-01-22)

The payment amounts for the non-drug component of the bundled payment for an episode of care, and the adjustments for counseling or therapy, intake activities, periodic assessments, and take-home supplies of naloxone (HCPCS codes G2067-G2077, G2080, *G2215, G2216, and G1028*) will be geographically adjusted using the Geographic Adjustment Factor.