

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10665</b>	<b>Date: March 16, 2021</b>
	<b>Change Request 12161</b>

**SUBJECT: Updates to Medicare Benefit Policy Manual and Medicare Claims Processing Manual for Opioid Treatment Programs (Manual Updates Only)**

**I. SUMMARY OF CHANGES:** This CR revises the Medicare Benefit Policy Manual, chapter 17, and the Medicare Claims Processing Manual, chapter 39, to reflect changes made in the Calendar Year (CY) 2021 Physician Fee Schedule Final Rule.

**EFFECTIVE DATE: January 1, 2021**

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

**IMPLEMENTATION DATE: April 15, 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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	39/Table of Contents
R	39/30/30.5/Site of service (telecommunications)
R	39/30/30.6/Coding
R	39/30/30.6.1/Adjustments to Bundled Payment Rate
R	39/30/30.7/Cost Sharing
R	39/30/30.8/Locality Adjustments
R	39/40/Claims submission

**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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## 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 CY 2020 Physician Fee Schedule Final Rule. CMS finalized additional OTP policies in the CY 2021 Physician Fee Schedule Final Rule.

**B. Policy:** This CR updates the Medicare Claims Processing Manual by making revisions to chapter 39, Opioid Treatment Programs (OTPs).

This CR updates the manual only.

## II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility							
		A/B MAC		D M E M A C	Shared- System Maintainers				Other
		A	B		H H H	F I S S	M C S	V M S	
12161 - 04.1	Medicare contractors shall be aware of changes to the Medicare Claims Processing Manual contained in this CR.	X	X						

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
	None					

#### IV. SUPPORTING INFORMATION

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

*"Should" denotes a recommendation.*

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
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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**

### **30.5 - Site of service (telecommunications)**

*(Rev. 10665: Issued; 03-16-21: Effective; 01-01-21: Implementation: 04-15-21)*

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, 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.* 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. 10665: Issued; 03-16-21: Effective; 01-01-21: Implementation: 04-15-21)*

The codes describing bundled payments made to OTPs are HCPCS codes G2067-G2075. There are add-on codes described by HCPCS codes G2076-G2080 *and HCPCS codes G2215 and G2216*. 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, we 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. We note that as HCPCS codes G2067 – G2075 cover episodes of care of 7 contiguous days, we 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, we do 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, we do 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.

We understand 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. We expect 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. 10665: Issued; 03-16-21: Effective; 01-01-21: Implementation: 04-15-21)*

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*.

We note 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, we do 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 (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.*

### **30.7 - Cost Sharing**

*(Rev. 10665: Issued; 03-16-21: Effective; 01-01-21: Implementation: 04-15-21)*

There is zero beneficiary copayment for *the* codes *billed by OTPs*. However, the Part B deductible does apply, as mandated for all Part B services by section 1833(b) of the Act.

### **30.8 - Locality Adjustments**

*(Rev. 10665: Issued; 03-16-21: Effective; 01-01-21: Implementation: 04-15-21)*

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, and G2216*) will be geographically adjusted using the Geographic Adjustment Factor.

### **40 - Claims submission**

*(Rev. 10665: Issued; 03-16-21: Effective; 01-01-21: Implementation: 04-15-21)*

*Beginning January 1, 2020, claims for OTP services are submitted using the 837P transaction to transmit health care claims electronically, or using the CMS-1500 (the paper version of the 837P). Beginning January 1, 2021, OTPs may apply on the Medicare Enrollment Application for Institutional Providers (CMS-855A) or through the Internet-based Provider Enrollment, Chain and Ownership System (PECOS) (837I) when they enroll in the Medicare Program. These providers will submit claims using the CMS-1450.*

HCPCS codes G2067-G2075 cover episodes of care of 7 continuous days and cannot be billed for the same patient more than once per 7 continuous day period.

HCPCS codes G2076-G2080 are add-on codes that are billed in addition to one of the base bundle codes described by HCPCS codes G2067-G2075.

Consistent with FDA labeling, HCPCS codes G2069 and G2073 should not be used more than once every 4 weeks and HCPCS codes G2070 and G2072 should not be used more than once every 6 months. HCPCS codes G2078 and G2079 may be billed in multiple units, up to 3 in one month (in addition to the base bundle code).

*HCPCS codes G2215 and G2216 are limited to being billed once every 30 days, however, exceptions to this limit are allowed in the case where the beneficiary overdoses and uses the initial supply of naloxone*

*dispensed by the OTP to the extent that it is medically reasonable and necessary to furnish additional naloxone. If an additional supply of naloxone is needed within 30 days of the original supply being provided, OTPs must document in the medical record the reason for the exception.  
HCPCS code G2216 (injectable naloxone) is contractor-priced for CY 2021.*

Patients may be appropriately given OUD services at more than one OTP within a 7 day period in certain limited clinical situations, such as for guest dosing or when a patient transfers care between OTPs. Each of the involved OTPs may bill the appropriate HCPCS codes for the services provided to the patient, but both OTPs must maintain sufficient medical record documentation to reflect the clinical situation and services provided.

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.