

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 4524	Date: February 14, 2020
	Change Request 11620

SUBJECT: Update to Medicare Benefit Policy Manual and Medicare Claims Processing Manual Adding New Chapters for Opioid Treatment Programs (Manual Updates Only)

I. SUMMARY OF CHANGES: This Change Request (CR) updates the Medicare Claims Processing Manual by adding a new chapter, Chapter 39, Opioid Treatment Programs (OTPs).

EFFECTIVE DATE: January 1, 2020

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

IMPLEMENTATION DATE: March 16, 2020

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	39/Table of Contents
N	39/10/General
N	39/20/Statutory authority for OTPs billing Medicare
N	39/30/Bundled payments for Opioid Use Disorder (OUD) treatment services
N	39/30.1/Duration of bundle
N	39/30.2/Requirements for an Episode
N	39/30.3/Non-drug episode of care
N	39/30.4/New drugs
N	39/30.5/Site of service (telecommunications)
N	39/30.6/Coding
N	39/30.6.1/Adjustments to Bundled Payment Rate
N	39/30.7/Cost Sharing
N	39/30.8/Locality Adjustments
N	39/30.9/Annual Updates
N	39/40/Claims submission
N	39/40.1/Place of Service
N	39/40.2/Date of Service
N	39/40.3/Prescribing Individuals

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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IMPLEMENTATION DATE: March 16, 2020

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. CMS finalized policies related to implementing this new benefit in the Calendar Year (CY) 2020 Physician Fee Schedule Final Rule.

B. Policy: This Change Request (CR) updates the Medicare Claims Processing Manual by adding a new chapter, 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	Shared- System Maintainers				Other
		A	B	H H H	M A C	F I S S	M C S	V M S	C W F
11620 - 04.1	Medicare contractors shall be aware of changes to the Medicare Claims Processing Manual contained in this CR.		X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H	M A C	
	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)

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10 - General

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

This chapter provides claims processing instructions for Opioid Treatment Programs (OTPs).

The Medicare Benefit Policy Manual, Chapter 17, provides coverage policy for OTPs.

20 - Statutory authority for OTPs billing Medicare

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

Section 2005 of the SUPPORT Act amended section 1861 of the Act by adding a new subsection (jjj)(2) to define an OTP as an entity meeting the definition of OTP in 42 CFR 8.2 or any successor regulation (that is, a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1)), that meets the additional requirements set forth in subparagraphs (A) through (D) of section 1861(jjj)(2) of the Act. Specifically that the OTP: is enrolled under section 1866(j) of the Act; has in effect a certification by the Substance Abuse and Mental Health Services Administration (SAMHSA) for such a program; is accredited by an accrediting body approved by SAMHSA; and meets such additional conditions as the Secretary may find necessary to ensure the health and safety of individuals being furnished services under such program and the effective and efficient furnishing of such services.

We defined “opioid treatment program” at § 410.67(b) as an entity that is an OTP as defined in § 8.2 (or any successor regulation) that meets the applicable requirements for an OTP. For an OTP to participate and receive payment under the Medicare program, the OTP must be enrolled under section 1866(j) of the Act, have in effect a certification by SAMHSA for such a program, and be accredited by an accrediting body approved by SAMHSA.

30 - Bundled payments for Opioid Use Disorder (OUD) treatment services

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

The bundled payment rates are calculated by combining the drug component and the non-drug components.

30.1 - Duration of bundle

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

An episode of care is defined at § 410.67(b) as a 1-week (contiguous 7-day) period.

There is no maximum number of weeks for a course of treatment for OUD.

30.2 - Requirements for an Episode

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

In recognition that there is a range of service intensity depending on the severity of a patient’s OUD and stage of treatment, a “full weekly bundle” may consist of a very different frequency of services for a patient in the initial phase of treatment compared to a patient in the maintenance phase of treatment, or based on other factors such as pregnancy or relapse.

The threshold to bill the weekly episode is the delivery of at least one service in the weekly bundle (from either the drug or non-drug component) to the patient during the week that corresponds to the episode of care. If no drug was provided to the patient during that episode, the OTP must bill the G-code describing the weekly bundle not including the drug (HCPCS code 2074) and the threshold to bill would be at least one service in the non-drug component. If a drug was provided with or without additional non-drug component services, the appropriate G-code describing the weekly bundle that includes the drug furnished may be billed.

30.3 - Non-drug episode of care

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

HCPCS code G2074 describes a non-drug episode of care. This provides a mechanism for OTPs to bill for non-drug services, including substance use counseling, individual and group therapy, and toxicology testing, that are rendered during weeks when a medication is not administered, for example, in cases where a patient is being treated with injectable buprenorphine or naltrexone on a monthly basis or has a buprenorphine implant.

30.4 - New drugs

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

We anticipate that there may be new Food and Drug Administration (FDA)-approved opioid agonist and antagonist treatment medications to treat OUD in the future.

OTPs may bill for an episode of care using the medication not otherwise specified (NOS) code (HCPCS code G2075) in the scenario where an OTP furnishes MAT using a new FDA-approved opioid agonist or antagonist medication for OUD treatment that is not specified in one of our existing codes. In such cases, the typical or average maintenance dose would be used to determine the drug cost for the new bundle, which contractors would then add to the non-drug component payment amount that corresponds with the relevant payment for drug administration (oral, injectable, or implantable) to determine the total bundled payment for the episode of care. Pricing for the drug component should be determined based on the relevant pricing methodology as described in the CY 2020 Physician Fee Schedule final rule or through invoice pricing in the event the information necessary to apply the relevant pricing methodology is not available.

30.5 - Site of service (telecommunications)

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

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 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. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

The codes describing bundled payments made to OTPs are HCPCS codes G2067-G2075. There are add-on codes described by HCPCS codes G2076-G2080. 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. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20))

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

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.*

30.7 - Cost Sharing

((Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20))

There is zero beneficiary copayment for HCPCS codes G2067-G2080. 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. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20))

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 and periodic assessments (HCPCS codes G2067-G2077, and G2080) will be geographically adjusted using the Geographic Adjustment Factor.

30.9 - Annual Updates

((Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20))

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 and periodic assessments (HCPCS codes G2067-G2077, and G2080) will be updated annually using the Medicare Economic Index.

40 - Claims submission

((Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20))

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).

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).

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.

40.1 - Place of Service

((Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20))

Claims for OTP services should use Place of Service code 58 (Non-residential Opioid Treatment Facility – a location that provides treatment for OUD on an ambulatory basis. Services include methadone and other forms of MAT).

40.2 - Date of Service

((Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20))

For the codes that describe a weekly bundle (HCPCS codes G2067-G2075), one week is defined as 7 contiguous days. OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care. In this case, the date of service would be the first day of the OTP's billing cycle. If a beneficiary starts treatment at the OTP on a day that is in the middle of the OTP's standard weekly billing cycle, the OTP may still bill the applicable code for that episode of care provided that the threshold to bill for the code has been met.

Alternatively, OTPs may choose to adopt weekly billing cycles that vary across patients. Under this approach, the initial date of service will depend upon the day of the week when the patient was first admitted to the program or when Medicare billing began. Therefore, under this approach of adopting weekly billing cycles that vary across patients, when a patient is beginning treatment or re-starting treatment after a break in treatment, the date of service would reflect the first day the patient was seen and the date of service for subsequent consecutive episodes of care would be the first day after the previous 7-day period ends.

For the codes describing add-on services (HCPCS codes G2076-G2080), the date of service should reflect the date that service was furnished; however, if the OTP has chosen to apply a standard weekly billing cycle, the date of service for codes describing add-on services may be the same as the first day in the weekly billing cycle.

40.3 - Prescribing Individuals

(Rev. 4524: Issued; 02-14-20: Effective; 01-01-20: Implementation: 03-16-20)

OTPs should list the prescribing or medication ordering physician's or other eligible professional's National Provider Identifier in Field 17 (the ordering/referring/other field) of the Form CMS-1500 (Health Insurance Claim Form; 0938-1197) or the digital equivalent thereof.