CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12418	**Date: December 21, 2023**
	Change Request 13470

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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to revise the Medicare Benefit Policy Manual, Chapter 17, and the Medicare Claims Processing Manual, Chapter 39, to reflect changes made in the CY 2024 Physician Fee Schedule Final Rule and and the CY 2024 Hospital Outpatient Prospective Payment System Final Rule.

EFFECTIVE DATE: January 1, 2024
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 24, 2024

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	17/20/Definitions relating to OTPs
R	17/40.1.1/40.1.1/Aspects of the bundle

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. 100-02	Transmittal: 12418	Date: December 21, 2023	Change Request: 13470

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

EFFECTIVE DATE: January 1, 2024
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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 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 2024 Physician Fee Schedule final rule and the CY 2024 Hospital Outpatient Prospective Payment System final rule.

B. Policy: This CR updates the Medicare Benefit Policy Manual by revising Chapter 17, OTPs.

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	
13470 - 02.1	Medicare contractors shall be aware of changes to the Medicare Benefit Policy Manual contained in this CR.	X	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:
	N/A

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

V. CONTACTS

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 Benefit Policy Manual
Chapter 17 - Opioid Treatment Programs (OTPs)

20 – Definitions relating to OTPs

(Rev. 12418; Issued: 12-21-23; Effective: 01-01-24; Implementation: 01-24-24)

A. Episode of care

Episode of care means a one-week (contiguous 7-day) period.

B. Opioid treatment program (OTP)

OTP means an entity that is an opioid treatment program (as defined in 42 CFR 8.2, or any successor regulation) that meets the requirements described in Section 30 - Requirements for OTPs.

C. Opioid use disorder (OUD) treatment service

OUD treatment service means one of the following items or services for the treatment of opioid use disorder that is furnished by an opioid treatment program that meets the requirements described in Section 30 - Requirements for OTPs.

1. Opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration (FDA) under section 505 of the Federal, Food, Drug, and Cosmetic Act (FFDCA) for use in treatment of opioid use disorder.

There are three drugs currently approved by the FDA for the treatment of opioid dependence: buprenorphine, methadone, and naltrexone.[1]

2. Dispensing and administration of opioid agonist and antagonist treatment medications, if applicable.

3. Substance use counseling by a professional to the extent authorized under State law to furnish such services including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

4. Individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law), including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements.

During the Public Health Emergency (PHE) for the COVID-19 pandemic, as well as after the conclusion of the PHE, therapy and counseling may be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology if two-way audio/video communications technology is not available to the beneficiary, provided all other applicable requirements are met, including circumstances in which the beneficiary is not capable of or does not consent to the use of devices that permit a two-way audio/video interaction.

5. Toxicology testing.

6. Intake activities, including initial medical examination services required under 42 CFR 8.12(f)(2) and initial assessment services required under 42 CFR 8.12(f)(4).

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[1] https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm600092.htm.

7. Periodic assessment services required under 42 CFR 8.12(f)(4) that are furnished during a face-to-face encounter, including, beginning on January 27, 2020, services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. The flexibility to furnish these services using two-way interactive audio-video communication technology was originally limited to services furnished during the PHE as defined in 42 CFR 400.200, but was subsequently made permanent effective beginning on January 1, 2021. During the PHE, as defined in 42 CFR 400.200, *and through the end of CY 2024,* 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 if all other applicable requirements are met.

8. Beginning January 1, 2021, opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

9. Beginning on January 1, 2024, OTP intensive outpatient services, which means one or more services specified in § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of OUD and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician or non-physician practitioner (as defined in section 1842(b)(18)(C) of the Act) certification and plan of care, as permitted by State law and scope of practice requirements, in which a physician or non-physician practitioner must certify that the individual has a need for a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services. OTP intensive outpatient services do not include FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, or toxicology testing.

D. OTP Mobile Units

Beginning January 1, 2023, services furnished via OTP mobile units will be considered for purposes of determining payments to OTPs under the Medicare OTP bundled payment codes and/or add-on codes to the extent that the services are medically reasonable and necessary and are furnished in accordance with SAMHSA and DEA guidance. For purposes of the geographic adjustment, OUD treatment services furnished via an OTP mobile unit will be treated as if the services were furnished at the physical location of the OTP registered with DEA and certified by SAMHSA.

40.1.1 Aspects of the bundle

(Rev. 12418; Issued: 12-21-23; Effective: 01-01-24; Implementation: 01-24-24)

A. Duration of the bundle

The duration of an episode of care for OUD treatment services is a week (that is, a contiguous 7-day period that may start on any day of the week).

1. Requirements for an episode

SAMHSA requires OTPs to have a treatment plan for each patient that identifies the frequency with which items and services are to be provided (§ 8.12(f)(4)). There is a range of service intensity depending on the severity of a patient's OUD and stage of treatment. The threshold to bill an episode of care will be that at least one OUD treatment service was furnished (from either the drug or non-drug component) to the patient during the week that corresponds to the episode of care, the OUD treatment services are described in Section 20 – Definitions relating to OTPs, C. Opioid use disorder treatment service. *For intensive outpatient services furnished by OTPs and described by HCPCS code G0137, the threshold to bill is a minimum of nine services over a 7-contiguous day period. The types of intensive outpatient services that would qualify to meet this threshold is described in § 410.67(b)(ix) in the definition of "OTP intensive outpatient services."*

2. Non-drug episode of care

In addition to bundled payments for an episode of care that are based on the medication administered for treatment (and include both a drug and non-drug component), the non-drug episode of care 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.

B. Drug and non-drug component

In establishing the bundled payment rates, CMS developed separate payment methodologies for the drug component and the non-drug component (which includes the dispensing and administration of medication, if applicable; substance use counseling; individual and group therapy; and toxicology testing) of the bundled payment. Each of these components is discussed in this section.

1. Drug component

The OTP bundled payment rates are based, in part, on the type of medication used for treatment. The categories reflect those drugs currently approved by the FDA under section 505 of the FFDCA for use in treatment of OUD: that is, methadone (oral), buprenorphine (oral), buprenorphine (injection), buprenorphine (implant), and naltrexone (injection)).

Additionally, as CMS anticipates that there may be new FDA-approved opioid agonist and antagonist treatment medications to treat OUD in the future. 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, the OTPs would bill for the episode of care using the medication not otherwise specified (NOS) code (HCPCS code G2075).

In such cases, CMS would use the typical or average maintenance dose 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. Please refer to Pub 100-04, Medicare Claims Processing Manual, Chapter 39 for claims processing information.

2. Non-drug component
Counseling, Therapy, Toxicology Testing and Drug Administration

The non-drug component of the OUD treatment services includes all items and services furnished during an episode of care except for the medication, specifically counseling, therapy, toxicology testing and drug administration.

OTPs must provide adequate substance abuse counseling to each patient as clinically necessary. Section 1861(jjj)(1)(C) of the Act, as added by section 2005(b) of the SUPPORT Act defines OUD treatment services as including "substance use counseling by a professional to the extent authorized under state law to furnish such services." Therefore, professionals furnishing therapy or counseling services for OUD treatment must be operating within State law and scope of practice. These professionals could include licensed professional counselors, mental health counselors, licensed clinical alcohol and drug counselors, licensed marriage and family therapists, and certified peer specialists that are permitted to furnish this type of therapy or counseling by state law and scope of practice. To the extent that the individuals furnishing therapy or counseling services are not authorized under state law to furnish such services, the therapy or counseling services would not be covered as OUD treatment services.

OTPs are required to provide adequate testing or analysis for drugs of abuse, including at least eight random drug abuse tests per year, per patient in maintenance treatment, in accordance with generally accepted clinical practice. These drug abuse tests (which are identified as toxicology tests in the definition of OUD treatment services in section 1861(jjj)(1)(E) of the Act) are used for diagnosing, monitoring and evaluating progress in treatment. The testing typically includes tests for opioids and other controlled substances.
Urinalysis is primarily used for this testing; however, there are other types of testing such as hair or fluid analysis that could be used. Any of these types of toxicology tests (such as presumptive and definitive toxicology tests) would be considered to be OUD treatment services and would be included in the bundled payment for services furnished by an OTP.

The non-drug component of the bundle also includes the cost of drug dispensing and/or administration, as applicable.

C. Adjustment to the bundled payment rates

Bundled payment rates may be adjusted by use of add-on codes for intake activities, periodic assessments, take-home supplies of methadone, take-home supplies of oral buprenorphine, additional counseling or group or individual therapy to be furnished for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan*, and intensive outpatient program services*.

If the OTP furnishes a take-home supply of opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication, an adjustment to the bundled payment rates will be made when these medications are dispensed. The adjustment will be limited to once every 30 days, except when a further take-home supply of these medications is medically reasonable and necessary. The opioid treatment program must document in the medical record the reason(s) for the exception.

OTPs that furnish intensive outpatient program services must meet the requirements stated in the definition of OTP intensive outpatient services at §410.67(b)(ix), in the certification and plan of treatment at §410.67(c)(5), and in the billing threshold mentioned at §410.67(4)(i)(F).

Additional information regarding the add-on codes can be found at Pub 100-04, Medicare Claims Processing Manual, Chapter 39.

D. Site of service (telecommunications)

OTPs are allowed to furnish the substance use counseling, individual therapy, and group therapy included in the bundle via two-way interactive audio-video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries. In addition, initiation of treatment with buprenorphine (but not methadone) via the OTP intake add-on code may be furnished via two-way audio-video communications technology to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. For additional information please refer to Section 20 – Definitions relating to OTPs, C. Opioid use disorder treatment service. During the Public Health Emergency (PHE) for the COVID-19 pandemic, as well as after the conclusion of the PHE, therapy and counseling may be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology if two-way audio/video communications technology is not available to the beneficiary, provided all other applicable requirements are met, including circumstances in which the beneficiary is not capable of or does not consent to the use of devices that permit a two-way audio/video interaction.

Beginning January 1, 2021, OTPs are allowed to use two-way interactive audio-video communication technology, as clinically appropriate, to furnish the periodic assessment add-on code. Additionally, during the PHE *which expired on May 11, 2023*, in cases where a beneficiary did not have access to two-way audio-video communications technology, periodic assessments could be furnished using audio-only telephone calls if all other applicable requirements were met. *Through the end of CY 2024, 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 if all other applicable requirements are met.*

Beginning January 1, 2023, OTPs are allowed to furnish the OTP intake add-on code via two-way audio- video communication technology when billed for the initiation of treatment with buprenorphine, to the extent that the use of audio-video telecommunications technology to initiate treatment with buprenorphine is authorized by DEA and SAMHSA at the time the service is furnished. OTPs are also allowed to use audio- only communication technology to initiate treatment with buprenorphine in cases where audio-video technology is not available to the beneficiary, including 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.

OTPs providing intensive outpatient services to Medicare beneficiaries with an OUD shall not receive payment under Medicare part B if the intensive outpatient services are furnished via audio-video or audio-only communications technology.

Telemedicine services should not, under any circumstances, expand the scope of practice of a healthcare professional or permit practice in a jurisdiction (the location of the patient) where the provider is not licensed.

Counseling or therapy furnished via communication technology as part of OUD treatment services furnished by an OTP must not be separately billed by the practitioner furnishing the counseling or therapy because these services would already be paid through the bundled payment made to the OTP.

E. Coding

A coding structure for OUD treatment services was adopted that varies by the medication administered. 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.

*HCPCS code G0137**:** Intensive outpatient services; minimum of nine services over a 7- contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes, excluding opioid agonist and antagonist medications that are FDA-approved for use in treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services (not including toxicology testing); (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure, if applicable.*

Only an entity enrolled with Medicare as an OTP can bill these codes. OTPs are limited to billing only these codes describing bundled payments, and may not bill for other codes, such as those paid under the Medicare Physician Fee Schedule (PFS).

F. Payment Rates
The codes describing the OTP bundled services (HCPCS codes G2067-G2075) are assigned flat dollar payment amounts. The payment rates for OUD treatment services are derived by combining the cost of the drug and the non-drug components (as applicable) into a single bundled payment as described in more detail below.

1. Drug component

As part of determining a payment rate for the bundles for OUD treatment services, a dosage of the applicable medication was selected in order to calculate the cost of the drug component of the bundle. In order to determine the drug costs for the weekly bundles, the following typical or average maintenance dosages were used:

• a 100 mg daily dose for methadone,

• a 16 mg daily dose for oral buprenorphine
• a 100 mg monthly dose for the extended-release buprenorphine injection,
• four rods each containing 74.2 mg of buprenorphine for the 6-month buprenorphine implant, and
• a 380 mg monthly dose for extended-release injectable naltrexone)
• Nasal naloxone is supplied as a single-dose intranasal spray containing 2mg, 4mg, or 8mg of naloxone hydrochloride in 0.1mL.[3] Nasal naloxone is packaged in a carton containing two doses to allow for repeat dosing if needed.
• Effective January 1, 2021, injectable naloxone is contractor priced. CMS may establish national pricing for injectable naloxone through future rulemaking. According to the package insert[45], an initial dose of 0.4 mg to 2 mg of injectable naloxone may be administered through intravenous, intramuscular, or subcutaneous routes. If needed, it may be repeated at two- to three-minute intervals up to a total dose of 10mg.

Drug Pricing Data Source

For Part B drugs, use the methodology in section 1847A of the Act (which bases most payments on average sales price (ASP)) to set the payment rates for the "incident to" drugs and limit the payment amounts for these drugs to 100 percent of the volume-weighted ASP for a drug category or code, and beginning January 1, 2021, the payment must be 100 percent of wholesale acquisition cost (WAC), if WAC is used.

For oral drugs, use ASP-based payment to set the payment rates for the oral product categories when CMS receives manufacturer-submitted ASP data for these drugs and limit the payment amounts for oral drugs to 100 percent of the volume-weighted ASP. When ASP data are not available for the oral drugs used in OTPs, use the National Average Drug Acquisition Cost (NADAC) data to set the payment for the drug component of the oral buprenorphine bundle.

For CY 2022, CMS established a limited exception to the current methodology for determining the payment amount for the drug component of an episode of care in order to freeze the payment amount for methadone furnished during an episode of care in CY 2022 at the payment amount that was determined for CY 2021.

Beginning January 1, 2023, the methodology for pricing the drug component of the methadone weekly bundle and the add-on code for take-home supplies of methadone will be based on and updated annually by the Producer Price Index (PPI) for Pharmaceuticals for Human Use (Prescription). The TRICARE rate will no longer be an alternative pricing methodology for methadone after January 1, 2023.

2. Non-drug component

The payment rate for the non-drug component is calculated based on a building block methodology using the Medicare payment rates for similar services furnished in the non-facility setting. Additionally, the non-drug component rate is adjusted to account for different administration and dispensing costs of the drug that is used in the episode of care (either oral, injectable, or implantable. The rate for dispensing oral drugs is determined using an approximation of the average dispensing fees under state Medicaid programs, which is $10.50, since there is no Medicare Part B rate for oral MAT drugs. The payment for the non-drug component of weekly bundles that include injectable drugs (buprenorphine and naltrexone) will include the Medicare non-facility rate for administration of an injection.

Medication not otherwise specified

The payment for the non-drug component of the medication not otherwise specified bundle is based on

whether the drug is oral, injectable, or implantable. This payment uses the building block payment methodology to determine the non-drug component of the bundled payments for medications that have the same mode of administration.

3. Place of Service (POS) Code for Services Furnished at OTPs

POS code specific to OTPs was created since there were no existing POS codes that specifically describe OTPs:

• 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).

CMS expects that POS code 58 will be noted on claims submitted for the HCPCS G codes describing OTP services. Additionally, the G codes describing the OTP bundled payments and add-on codes can only be billed by OTPs and cannot be billed by other providers. POS codes are not limited to Medicare use and may be used by other payers.

In regards to non-OTP pharmacies dispensing MAT drugs included in an OTP bundle, CMS encourages pharmacies and prescribing OTPs to be in close communication in order to ensure proper billing procedures are followed and to prevent duplicative payments. The presence of POS code 58 on retail pharmacy claims will not mean that the pharmacy should process MAT claims any differently than they do now.

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[3] https://www.narcan.com/static/Gen2-Prescribing-Information.pdf

[4] http://labeling.pfizer.com/ShowLabeling.aspx?id=4541

[5] https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f0932877-1f3b-4d5e-82d2-dd6c53db4730&type=display.