Opioid Treatment Programs

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Introduction & Instructions for Use

Introduction

Medicare Coverage Summaries are a set of objective and evidence-based behavioral health criteria used by medical necessity plans to standardize coverage determinations, promote evidence-based practices, and support members' recovery, resiliency, and wellbeing for Medicare behavioral health benefit plans managed by Optum®.

Instructions for Use

This guideline is used to make coverage determinations as well as to inform discussions about evidence-based practices and discharge planning for behavioral health benefit plans managed by Optum. When deciding coverage, the member's specific benefits must be referenced.

All reviewers must first identify member eligibility, the member-specific benefit plan coverage, and any federal or state regulatory requirements that supersede the member's benefits prior to using this guideline. In the event that the requested service or procedure is limited or excluded from the benefit, is defined differently or there is otherwise a conflict between this guideline and the member's specific benefit, the member's specific benefit supersedes this guideline. Other clinical criteria may apply. Optum reserves the right, in its sole discretion, to modify its clinical criteria as necessary using the process described in Clinical Criteria.

This guideline is provided for informational purposes. It does not constitute medical advice.

Optum may also use tools developed by third parties that are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Optum may develop clinical criteria or adopt externally-developed clinical criteria that supersede this guideline when required to do so by contract or regulation.

If there is an absence of any applicable Medicare statutes, regulations, National or Local Coverage Determinations offering guidance, Optum utilizes adopted external criteria as follows:

- Level of Care Utilization System (LOCUS):
    - Standardized level of care assessment tool developed by the American Association of Community Psychiatrists used to make determinations and placement decisions for adults ages eighteen and older.
- Child and Adolescent Level of Care/Service Intensity Utilization System (CALOCUS-CASII):
    - Standardized assessment tool developed by the American Academy of Child and Adolescent Psychiatry and the American Association of Community Psychiatrists used to make determinations and to provide level of service intensity recommendations for children and adolescents ages 6-18.
    - Access the CALOCUS-CASII Criteria here
- Early Childhood Service Intensity Instrument (ECSII):
    - Standardized assessment tool developed by the American Academy of Child and Adolescent Psychiatry used to make determinations and to provide level of service intensity recommendations for children ages 0-5.
    - Access the ECSII Criteria here

National criteria that stem from evaluation of new services or treatments or new applications of existing services or treatments and are used to make coverage determinations regarding experimental and investigation services and treatments. Optum Behavioral Clinical Policies:

- Complementary and Alternative Medicine (CAM) Treatments
- Computer Based Treatment for Cognitive Behavioral Therapy (CBTCBT)
- Neurofeedback
- Transcranial Magnetic Stimulation
- Wilderness Therapy

- *Optum utilizes The ASAM Criteria to supplement the Medicare National Coverage Determinations (NCDs 130.1-130.7) for Alcohol and Substance Abuse Treatment to ensure consistency in making medical necessity determinations.*
    - Access the ASAM Criteria *here*

Use of The ASAM Criteria to supplement the general provisions outlined under 42 CFR 422.101(b)(6)(i) provides clinical benefits that are highly likely to outweigh any clinical harms from delayed or decreased access to items or services.

Specifically, The ASAM Criteria are consulted when the NCDs do not fully address the type of treatment or appropriate treatment setting that will likely lead to improvement of the member's condition. The ASAM Criteria are also consulted due to the comprehensive six-dimension analysis to determine if comorbid medical, mental health and substance related factors add to the evidence for services not offered in the NCDs.

These criteria represent current, widely used treatment guidelines developed by organizations representing clinical specialties, or Optum developed criteria based on "acceptable clinical literature" according to 422.101(b)(6)(i). Optum selects and uses clinical criteria that are consistent with generally accepted standards of care, including objective criteria that are based on sound clinical evidence. Optum uses the criteria to make standardized coverage determinations and to inform discussions about evidence-based practices and discharge planning. The use of such criteria is highly likely to outweigh any clinical harms from delayed or decreased access to care.

Opioid Treatment Programs

Opioid Treatment Programs (OTPs) address the treatment of opiate use disorder (OUD) in non-residential opioid treatment facilities that provide treatment on an ambulatory basis. All OTP activities must be in accordance and comply with the applicable Code of Federal Regulations for Opioid Use Disorder Treatment (CMS L39849).

Applicable States

Note: Part A services are typically inpatient. Part B services are typically outpatient.

CMS L39849/A59718 (All states Part A Inpatient Services and Part B Outpatient Services apply)

- Alabama
- Georgia
- North Carolina
- South Carolina
- Tennessee
- Virginia
- West Virginia

Coverage, Indications, Limitation and/or Medical Necessity

Indications (CMS L39849, 2024)

- OTP treatment is considered reasonable and necessary for beneficiaries meeting all of the following requirements:
  - diagnosed with OUD using the Diagnostic and Statistical Manual for Mental Disorders, AND
  - voluntarily chooses maintenance treatment, AND
  - is currently addicted to an opioid drug

Initial Assessment

- Upon admission to the OTP and before initiating pharmacotherapy, the beneficiary must undergo an initial assessment as part of the intake activities. To qualify as an initial assessment the following must be addressed and included in the documentation:
  - Confirmation of the OUD diagnosis
  - Complete medical history inclusive of concomitant medical conditions, psychiatric disorders, trauma, infectious disease, and pregnancy
  - Physical exam (unless assessment is performed via telehealth)
  - Mental health screening for psychiatric disorders
  - Laboratory testing to include complete blood count, liver enzyme testing, tuberculosis screening, hepatitis B + C, and HIV. If laboratory testing is not performed, documentation of recent testing or the rationale for not testing must be included.
  - Authenticated informed consent inclusive of treatment options discussed, risk/benefit consideration of pharmacotherapy, and the patient's preferences for therapy.
  - Formation of treatment plan with discussion of psychosocial treatment, support, and patient's preference for these services.
  - Assessment of withdrawal potential and the associated plan.
  - Assessment of safety including overdose potential, prevention education, and offer of take-home naloxone.

Drug Testing

- Testing for drugs of abuse must be provided.
- The use of other addictive drugs of abuse should not be a reason to withhold or suspend OUD treatment. However, those who are actively using substances during OTP are likely to require greater support including a more intensive level of care.

Periodic Assessments

- Periodic assessments are required and must include documentation of the following:
  - Evaluation of treatment progress and appropriate adjustments in therapy
  - Review of drug abuse testing and assessment of compliance
  - Review of psychosocial needs and plan to address unmet needs (if any)
  - Documentation that substantiates necessity for a periodic visit

Duration of Treatment

- There is no limitation to the duration of treatment.
- All coverage criteria must be clearly documented in the patient's medical record and made available to the A/B MAC upon request.

Provider Qualifications

Covered Providers (L39849)

- Care must be provided by one or a combination of the following providers and take place as part of a certified opioid treatment program:
  - Physicians (MD/DO)
  - Clinical psychologists
  - Licensed Clinical Social Workers
  - Nurse practitioners
  - Clinical Nurse Specialists
  - Physician Assistants
  - Other providers of mental health services licensed or otherwise authorized by the state in which they practice (e.g., licensed professional counselors, licensed clinical alcohol and drug counselors, licensed marriage and family therapists, licensed clinical alcohol and drug counselors, certified peer specialists)

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Revision History

Date	Summary of Changes
December 17, 2024	Version 1; new MCS