Medicare Part B Utilization Management in the Absence of NCD or LCD

UM Committee Review	
Approved Dates	

Purpose

The purpose of this document is to provide a detailed account of the process for applying utilization management to Medicare Part B-eligible pharmaceutical products in the absence of an LCD or NCD.

Definitions

Acronym/Term	Definition
CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
LCA	Local Coverage Article
LCD	Local Coverage Determination
MAC	Medicare Administrative Contractor
MAO	Medicare Advantage Organization
NCD	National Coverage Determination
PA	Prior Authorization
UM	Utilization Management

A. CMS Guidance

1. Pub. 100-16, Chapter 4, Sec. 10.2 Basic Rule, Medicare coverage and payment is contingent upon a determination that:
   a. A service is in a covered benefit category;
   b. A service is not specifically excluded from Medicare coverage by the Act; and
   c. The item or service is “reasonable and necessary” for the diagnosis or treatment of an illness or injury, to improve the functioning of a malformed body member, or is a covered preventive service.
2. Pub. 100-16, Chapter 4, Sec. 10.16 Medical Necessity (42 CFR §422.112(a)(6)(ii)); MA organizations must establish written standards for policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determination.

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3. Pub. 100-16, Chapter 4, Sec. 90.1 National and Local Coverage Determination Overview; an item or service classified as an original Medicare benefit must be covered by every MA plan if:
   a. Its coverage is consistent with general coverage guidelines included in original Medicare regulations, manuals, and instructions (unless superseded by written CMS instructions or regulations regarding Part C of the Medicare program)
   b. It is covered by CMS's national coverage determinations (see sections 90.3 and 90.4, below); or
   c. It is covered by written coverage decisions of local Medicare Administrative Contractors (MACs) with jurisdiction for claims in the geographic area in which services are covered under the MA plan, as described in section 90.2 below.
4. Pub. 100-16, Chapter 4, Sec. 90.5 Creating New Guidance, in coverage situations where there is no NCD, LCD, or guidance on coverage in original Medicare manuals, an MA organization:
   a. May adopt the coverage policies of other MAOs in its service area; OR
   b. Must make its own coverage determination and provide CMS an objective evidence based rationale relying on authoritative evidence.
5. 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F) specifies that all MA plans establish a Utilization Management Committee to review all utilization management, including prior authorization, policies annually and ensure they are consistent with the coverage requirements, including current, traditional Medicare's national and local coverage decisions and guidelines. Refer to § 422.137 Medicare Advantage Utilization Management Committee

B. Application of Guidance

1. Pursuant to A.3.b. and A.3.c. above, the respective CMS coverage determinations are referenced (if available) in determining A.1.a through A.1.c. above (these may be found at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx).
   a. Per Pub. 100-16, Chapter 4, Sec. 90.4.2 Multiple A/B MACs with Different Policies, the coverage policy with jurisdiction over the state in which the service is furnished to the enrollee is applied, OR
   b. The MA plan adopts a uniform coverage policy for all enrollees which is subsequently communicated to CMS (CMS approval is required for local, but not regional, MA plans).
      i. Upon plan direction, the specified uniform coverage policy is applied to providers within the plan's service area.
      ii. For providers not within the plan's service area, local coverage determination based on the provider's geographic location is used per B.1.a. above; OR
2. Pursuant to A.3.a. above, in the absence of superseding written CMS instructions or regulations regarding Part C of the Medicare program, original Medicare manual Pub. 10002, Chapter 15, Sec. 50 Drugs and Biologicals is applied.

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a. Pub. 100-02, Chapter 15, Sec. 50.4.1 Approved Use of Drug: Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA-approved drug or biological, if:

   i. It was injected on or after the date of the FDA's approval.

   ii.

   ii. It is reasonable and necessary for the individual patient;

   and

   iii. All other applicable coverage requirements are met, OR

b. Medicare Part B does not cover drugs that are usually self-administered by the patient pursuant to Pub. 100-02, Chapter 15, Sec. 50.2 unless the statute provides for such coverage pursuant to Pub. 100-02, Chapter 15, Sec. 50.5.

   i. Refer to Pub. 100-02, Chapter 15, Sec. 50.5.1 through 50.5.5 for statutorily covered self-administered drugs.

   ii. Refer to Pub. 100-02, Chapter 15, Sec. 50.2 for determining if a drug or biological meets the requirement under Part B that they are not usually self-administered by the patient.

      1. Additionally, MACs may publish a self-administered drug exclusions list LCA to provide guidance.

c. Off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is covered pursuant to Pub. 100-02, Chapter 15, Sec. 50.4.5. Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. In general, use is identified by a compendium as medically accepted if:

   i. The indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex (Merative Micromedex); or,

   ii. Narrative text in AHFS-DI or Clinical Pharmacology is supportive, or

   iii. The indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"

   A use is not medically accepted by a compendium if:

   i. The indication is a Category 3 in NCCN or a Class III in DrugDex (Merative Micromedex); or,

   ii. Narrative text in AHFS or Clinical Pharmacology is "not supportive," or

   iii. The indication is listed in Lexi-Drugs as "Use: Unsupported"

   The complete absence of narrative text on a use is considered neither supportive nor non-supportive.
   Note: Requests for NCCN category 2B indications will be evaluated based upon medical necessity on a case-by-case basis; OR

d. Off-label use of drugs and biologicals NOT in an anti-cancer chemotherapeutic regimen is evaluated according to A.4. above:

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i. Per A.4.a., the MA plan adopts the coverage policies of other MAOs in its service area; OR

ii. Per A.4.b., the MA plan must make its own coverage determination. In this instance, the MAO does one of the following:

1. Adopts the coverage policies for off-label uses from another MAC: L33394 (NGS; Jurisdiction 6) and/or L33915 (First Coast; Jurisdiction N[9]) if these are within its service area (MAC service areas may be found at: https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Who-are-theMACs); OR

2. Determines coverage for medically accepted use by following the process described for determining coverage under Medicare used by the A/B MAC (B) per Pub. 100-02, Chapter 15, Sec. 50.4.2 Unlabeled Use of Drug, which provides for taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. Support in one or more compendia is defined as follows:

a. The indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex (Merative Micromedex); OR

i. Note: Requests for NCCN category 2B indications will be evaluated based upon medical necessity on a case-bycase basis

b. Narrative text in AHFS-DI or Clinical Pharmacology is supportive, OR

c. The indication is listed in Lexi-Drugs as “Use: Off-Label” and rated as “Evidence Level A”; OR

3. Determines coverage for medically accepted use based upon the Plan’s clinical criteria for other non-Medicare lines of business.

3. Pursuant to A.5. above, for 2024, each MA Plan must establish a Utilization Management Committee to review all utilization management, including prior authorization, policies annually and ensure they are consistent with the coverage requirements, including current, traditional Medicare national and local coverage decisions and guidelines.

Procedure for PA Review

Utilization management review and determination of “reasonable and necessary” in the absence of an NCD or local coverage document from the MAC, occurs via the Medicare Part B Utilization Management Review document.

- CMS-4201-F §422.112(b)(8) specifies for 2024:
  A minimum 90-day transition period shall be provided when an enrollee who is currently undergoing an active course of treatment switches to a new MA plan.

Utilization management review for Medicare Part B occurs via a stepwise approach as follows:

1. Determination of “reasonable and necessary”
   a. Refer to the Medicare Coverage Database (MCD) for a national coverage determination

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(NCD) or local coverage determination (LCD) from the Medicare Administrative Contractor (MAC) for the jurisdiction

b. In the absence of an NCD or LCD, the FDA-approved product label is referenced for ALL of the following:
    i. Indication (including age restrictions)
    ii. Dose and frequency
    iii. Duration of therapy (if limited)
    iv. Boxed warnings
    v. Contraindications (with the exception of hypersensitivity to the requested product)
    vi. Warnings and Precautions (with the exception of those which would only become apparent/applicable upon receipt of the product as this occurs subsequent to the pre-service determination)

c. Off-label use (inclusive of dose, frequency, and duration) reference the following: i. Oncology
    1. CMS-supported compendia (i.e., NCCN, Clinical Pharmacology, Lexicomp Lexi-Drugs, Micromedex DrugDex (Merative Micromedex), & AHFS-DI) or published peer-reviewed literature

    ii. Non-Oncology
    1. CMS-supported compendia (i.e., NCCN, Clinical Pharmacology, Lexicomp Lexi-Drugs, Micromedex DrugDex (Merative Micromedex), & AHFS-DI), authoritative medical literature and/or accepted standards of medical practice

2. Once “reasonable and necessary” has been determined, refer to the Medicare Part B Step Therapy document for preferred agents (as applicable).
    a. Exceptions to step therapy include any of the following:
        i. Use of the non-preferred product in the preceding 365 days.
        ii. Documented failure, contraindication, or intolerance to [CLIENT- specific: all, one, two, etc.] preferred products.
        iii. Documentation that all preferred products are likely to be ineffective or cause an adverse reaction.
        iv. The medically accepted indication for use is not shared amongst products by either FDA labeling or CMS-recognized compendia or clinical literature.

3. The authorization validity period for 2024 must conform to that specified by CMS or the MAC. In the absence of such, it shall be determined based upon the prescriber’s anticipated course of therapy, unless there is a superseding limitation to the duration in the source used to

    determine reasonable and necessary (refer to 1.b. and 1.c. above). Prior to 2024, the validity period is at the discretion of the MAO (Medicare Advantage Organization).

4. Requests for continuation of therapy shall assess beneficial response to therapy and the absence of unacceptable toxicities for a medically accepted indication.

5. The clinician reviewer considers all relevant aspects of the case and patient-specifics when making the determination. The clinician reviewer may exercise clinical judgment and apply it to the pre-service determination. Such applications will be clearly documented in the case file notes.

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Note:

• The above may in whole or in part, at the discretion of Prime Therapeutics, LLC, be incorporated into a decision support tool to assist in the expedient collection of pertinent information for favorable coverage determination (Note: adverse coverage determination cannot be rendered by a decision-support tool).

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