Medicare Part B Utilization management in absence of NCD or LCD

Policy and Procedure Data

Original Effective Date	01/01/2024
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Scope	Medicare Part B Medication prior authorization review

Policy statement

It is Medica's policy to have written standards, policies and procedures that comply with the U.S. Federal Sentencing Guidelines, Centers for Medicare and Medicaid Services (CMS) g uidance, Affordable Care Act requirements governing federally-facilitated and state-based marketplaces, and all other state and federal regulations.
The 2024 Medicare Advantage and Part D Final Rule (CMS-4201-F) specifies that all MA plans establish a Utilization Management (UM) 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. This policy aligns utilization management authorization of non-CMS managed Therapeutic categories for Medica's Part B pharmaceutical products that the Utilization Management (UM) committee will apply consistent, unbiased and sound guidance for application.

Purpose

The purpose of this policy and procedure is to establish a process for documenting the review and approval of the assignment of a utilization management to a Medicare Part B-eligible pharmaceutical products in the absence of an LCD (Local coverage determination) or NCD (National Coverage determination) as it relates to guidance in Medicare manual Pub. 100-02, Chapter 15, Sec. 50 Drugs and Biologicals Chapter. The CMS guidance will be used to apply utilization Management to new to market drugs for a Part B pharmaceutical product monthly to yearly for UM Committee to review and approve application.

Definitions

1.1 Medical Director – must be employed by Medica and must have a current and unrestricted license to practice in a State, territory, Commonwealth of the United States

1.2 Practicing Physician – any physician who has current and unrestricted license to practice in various clinical specialties in a State, territory, Commonwealth of the United States

1.3 Independent Physician - is a practicing physician who is free of conflict relative to the Medica organization and servicing plans.
1.4 CMS – Centers for Medicare and Medicaid services
1.5 LCD – Local Coverage Determinations
1.6 NCD – National coverage determination
1.7 PA – Prior Authorization
1.8 UM – Utilization Management
1.9 FDA – Food and drug administration
1.10 LCA – Local coverage article
1.11 MAC– Medicare administrative contractor
1.12 MAO- Medicare Advantage Organization
1.13 PA – Prior Authorization
1.14 UM – Utilization Management

Procedure

1.15 CMS Guidance

1.15.1 Pub. 100-16, Chapter 4, Sec. 10.2 Basic Rule, Medicare coverage and payment is contingent upon a determination that:

1.15.1.1 A service is in a covered benefit category;

1.15.1.2 A service is not specifically excluded from Medicare coverage by the Act; and

1.15.1.3 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.

1.15.2 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.

1.15.3 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:

1.15.3.1 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)

1.15.3.2 It is covered by CMS's national coverage determinations (); or

1.15.3.3 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.

1.15.4 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:

1.15.4.1 May adopt the coverage policies of other MAOs in its service area; OR

1.15.4.2 Must make its own coverage determination and provide CMS an objective evidence based rationale relying on authoritative evidence.

1.15.5 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

2.0 Application of Guidance

2.1.1 Pursuant to 1.15 (1.15.3.2 and 1.15.3.3) above, the respective CMS coverage determinations are referenced (if available) in determining 1.15 (1.15.1.1-1.15.1.3)above (these may be found at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx).

2.1.1.1 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

2.1.1.2 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).

2.1.1.2.1 Upon plan direction, the specified uniform coverage policy is applied to providers within the plan's service area

2.1.1.2.2 For providers not within the plan's service area, local coverage determination based on the provider's geographic location is used per 2.1.1. above; OR

2.1.2 Pursuant to1.15.3.1 above, in the absence of superseding written CMS instructions or regulations regarding Part C of the Medicare program, original Medicare manual Pub. 100-02, Chapter 15, Sec. 50 Drugs and Biologicals is applied.

2.1.2.1 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:

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

2.1.2.1.2 It is reasonable and necessary for the individual patient; and

2.1.2.1.3 All other applicable coverage requirements are met, OR

2.1.2.2 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.

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

2.1.2.2.2 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.

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

2.1.2.3 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:

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

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

2.1.2.3.3 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:

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

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

2.1.2.3.6 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

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

2.1.2.4.1 Per1.15.4.1, the MA plan adopts the coverage policies of other MAOs in its service area; OR

2.1.2.4.2 Per1.15.4.2, the MA plan must make its own coverage determination. In this instance, the MAO does one of the following:

2.1.2.4.2.1 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: ttps://www.cms.gov/Medicare/MedicareContracting/Medicare-dministrative-Contractors/Who-are-theMACs); OR

2.1.2.4.2.2 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:

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

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

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

2.1.2.4.2.2.3 The indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"; OR

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

2.1.3 Pursuant to1.15.5 above, for 2024 and beyond, 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.

2.2 Procedure for PA Review

2.2.1.1 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 and beyond:

- 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 without requiring reauthorization.

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

2.2.2.1 Determination of "reasonable and necessary"

2.2.2.1.1 Refer to the Medicare Coverage Database (MCD) for a national coverage determination (NCD) or local coverage determination (LCD) from the Medicare Administrative Contractor (MAC) for the jurisdiction

2.2.2.1.2 In the absence of an NCD or LCD, the FDA-approved product label is referenced for ALL of the following:

2.2.2.1.2.1 Indication (including age restrictions)

2.2.2.1.2.2 Dose and frequency

2.2.2.1.2.3 Duration of therapy (if limited)

2.2.2.1.2.4 Boxed warnings

2.2.2.1.2.5 Contraindications (with the exception of hypersensitivity to the requested product)

2.2.2.1.2.6 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)

2.2.2.1.3 Off-label use (inclusive of dose, frequency, and duration) reference the following:

2.2.2.1.3.1 Oncology

2.2.2.1.3.1.1 CMS-supported compendia (i.e., NCCN, Clinical Pharmacology, Lexicomp Lexi-Drugs, Micromedex DrugDex (Merative Micromedex), & AHFS-DI) or published peer-reviewed literature

2.2.2.1.4 Non-Oncology

2.2.2.1.4.1 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

2.2.2.1.4.2 Once “reasonable and necessary” has been determined, refer to the Medicare Part B Step Therapy document for preferred agents (as applicable).

2.2.2.1.4.3 Exceptions to step therapy include any of the following:

2.2.2.1.4.3.1 Use of the non-preferred product in the preceding 365 days.

2.2.2.1.4.3.2 Documented failure, contraindication, or intolerance to [CLIENT- specific: all, one, two, etc.] preferred products.

2.2.2.1.4.3.3 Documentation that all preferred products are likely to be ineffective or cause an adverse reaction.

2.2.2.1.4.3.4 The medically accepted indication for use is not shared amongst products by either FDA labeling or CMS-recognized compendia or clinical literature.

2.2.2.1.5 The authorization validity period for 2024 and beyond 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).
2.2.2.1.6	Requests for continuation of therapy shall assess beneficial response to therapy and the absence of unacceptable toxicities for a medically accepted indication.
2.2.2.1.7	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.

Citations

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7) Services, Department of Health and Human Services. Subchapter B – Medicare Program. Part 422 –Medicare Advantage Program. Subpart C – Benefits and Beneficiary Protections. Section 422.112 –Access to services. 42 CFR §422.112(a)(6)(ii).
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21) NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) National Comprehensive Cancer Network, Inc. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org

Cross references

Medica Medical Policy Committee Charter
Pharmacy Department Medica Part B committee Review Policy/Procedure

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Policy History

Date	Description
1/2024	Creation of policy
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Signature

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