Medicare Part B
Prior Authorization

Medicare Part B Utilization Management Review

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 Medicare Advantage (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 (NCD) or local coverage determination (LCD) from the Medicare Administrative Contractor (MAC) for the jurisdiction
   b. In the absence of a NCD or LCD, the FDA-approved product label is referenced for ALL of the following:
      i. Indication (including age restrictions)
      ii. Dose, frequency, and any information important for safe and effective use
      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 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).

4. Requests for continuation of therapy shall assess beneficial response to therapy and the absence of dose-limiting 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 judgement and apply it to the pre-service determination. Such applications will be clearly documented in the case file notes.

Related Documents:

Procedure doc

References

1. Lexi-Drugs. Lexicomp [Internet]. Hudson, OH: Wolters Kluwer Health, Inc. Available from: http://online.lexi.com
2. Merative Micromedex (DRUGDEX). Micromedex [Internet]. Greenwood Village, CO: Truven Health Analytics, Inc. Available from: http://www.micromedexsolutions.com
3. Gold Standard, Inc. Clinical Pharmacology [Internet]. Philadelphia, PA: Elsevier. Available from: https://www.clinicalkey.com/pharmacology/
4. AHFS Drug Information. Bethesda, MD: American Society of Health-System Pharmacists, Inc. Available from: https://www.ahfscdi.com/login
5. 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

Document History
Original Prime Standard Part B PA criteria, approved by P&T UM Committee 02/2023
Annual Review Prime Standard Part B PA criteria, with changes to criteria, approved by P&T UM Committee 08/2023
Annual Review Prime Standard Part B PA criteria, with changes to criteria, approved by P&T UM Committee 08/2024