Medicare Medical Policy Development

Kaiser Permanente Medicare Advantage Medical Policies identify the clinical criteria for determining when medical services are considered ‘reasonable and necessary’ (medically necessary). Medicare Advantage plans are required by CMS to provide the same medical benefits to Medicare Advantage members as Original Medicare. As such, whenever possible, Medicare Advantage Medical Policies are based on Medicare coverage manuals, National Coverage Determinations (NCDs), and Local Coverage Determinations (LCDs) when available. If there is no applicable NCD or LCD for the service under review, then per CMS other evidence-based criteria may be applied. In addition, each member’s unique, clinical situation is considered in conjunction with current CMS guidelines.

Kaiser Permanente Medicare Medical Policy Hierarchy

The following hierarchy is used to determine Kaiser Permanente Medicare Advantage Medical Policy:

- **CMS Coverage Manuals or other CMS-based Resource**
  “Coverage provisions in interpretive manuals are instructions that are used to further define when and under what circumstances items or services may be covered (or not covered).”[3] Other CMS-based resources include, but are not limited to, documentation such as Medicare Learning Network (MLN) and Federal Register (FR) publications.

- **National Coverage Determinations (NCD)**
  For some services, procedures, and technologies, CMS has developed an NCD, which is to be applied on a national basis for all Medicare beneficiaries. Once published in a CMS program instruction, the NCD is binding on all Medicare Advantage plans.[4]

- **Local Coverage Determinations (LCD), Articles (LCA), and other contractor-based bulletins**
  When there is no NCD or other coverage provision outlining medical necessity criteria within a Medicare manual, or when there is a need to further define an NCD, then the Medicare Administrative Contractor (MAC) for a service area may develop an LCD. (5) Noridian Healthcare Solutions (Noridian) is the designated MAC for the state of Washington.

- **Retired LCD/LCD**
  LCDs are retired due to lack of evidence of current problems with utilization, or in some cases because the material is addressed by a National Coverage Determination (NCD), a coverage provision in a CMS interpretative manual or an article. Most LCDs are not retired because they are incorrect. The guidance in the retired LCD may still be helpful in assessing medical necessity.[10]

- **Commercial Medical Policies**
  In coverage situations where there is no NCD, LCD, or guidance on coverage in original Medicare manuals, a Medicare Advantage Organization (MAO) may adopt the coverage policies of other MAOs in its service area.[8]
  However, if the MAO decides not to use coverage policies of other MAOs in its service area, the MAO:
  - Must make its own coverage determination;
  - Must provide CMS an objective evidence-based rationale relying on authoritative evidence such as:
    - Studies from government agencies (e.g. the FDA);
    - Evaluations performed by independent technology assessment groups (e.g. BCBSA); and
    - Well-designed controlled clinical studies that have appeared in peer review journals; and
  - In providing its justification, the MAO may not use conclusory statements with no accompanying rationale (e.g., “It is our policy to deny coverage for this service.”)

- **MCG™ Care Guidelines**
  If no policy criteria are available within an NCD, LCD, coverage manual, or existing medical policy for the services in question, MCG™ guidelines may be applied at the discretion of the physician reviewer.
Kaiser Permanente may consider some services to have insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies. When a procedure or device is deemed to have “insufficient evidence” by the Kaiser Permanente, the term “insufficient evidence” does not mean the procedure or device has not been approved by the Food and Drug Administration (FDA). Rather, it means the procedure or device does not meet Kaiser Permanente’s objective, evidence-based technology assessment based on authoritative evidence. See the Kaiser Permanente Medical Technology Assessment Committee for further details regarding their evidence-based evaluation process.

Noridian may also provide coverage or non-coverage guidance in a Part B News Article published on the noridianmedicare.com website. Thus, these articles may be used in Medicare Advantage coverage decisions even though they are not in the form of an LCD or an LCA.

For some topics, an LCD or LCA from a MAC other than Noridian may be used, both due to unusual or extenuating circumstances, and in situations where it is required in order to remain compliant with CMS guidelines. For example, when a single contractor has exclusive jurisdiction over a Medicare covered item or service (e.g., when there is only one provider of a particular pathology or lab test), CMS requires the coverage requirements or LCD of the contractor for the provider’s geographical area be applied.(6)

For genetic and molecular diagnostic testing, Noridian has implemented the guidelines published by Palmetto GBA under the Molecular Diagnostic (MolDX) Program for their Jurisdiction F (J-F) service area.(7). MolDX guidelines, when available, should be applied to requests for genetic and molecular diagnostic testing. In the absence of a guideline for a genetic test the above hierarchy will apply.

References:
1. Title XVIII of the Social Security Act, §1862(a)(1)(A)
2. Noridian LCD for Non-Covered Services (L35008) (This LCD can be found on the Medicare Coverage Database website)
3. Medicare Program Integrity Manual, Pub. #100-08, Chapter 13 – Local Coverage Determinations, §13.1.2 - Coverage Provisions in Interpretive Manuals
4. Medicare Program Integrity Manual, Pub. #100-08, Chapter 13 – Local Coverage Determinations, §13.1.1 - National Coverage Determinations (NCDs)
5. Medicare Program Integrity Manual, Pub. #100-08, Chapter 13 – Local Coverage Determinations, §13.1.3 - Local Coverage Determinations (LCDs)
6. Medicare Managed Care Manual, Pub. #100-16, Chapter 4 - Benefits and Beneficiary Protections, §90.4.1 – MACS with Exclusive Jurisdiction over a Medicare Item or Service
8. Medicare Managed Care Manual, Pub. #100-16, Chapter 4 - Benefits and Beneficiary Protections, §90.5 - Creating New Guidance

[8] - 90.5 – Creating New Guidance
(Rev. 120, Issued: 01-16-15, Effective: 01-01-15, Implementation: 01-01-15)
In coverage situations where there is no NCD, LCD, or guidance on coverage in original Medicare manuals, a Medicare Advantage Organization (MAO) may adopt the coverage policies of other MAOs in its service area. However, if the MAO decides not to use coverage policies of other MAOs in its service area, the MAO:
- Must make its own coverage determination;
- Must provide CMS an objective evidence-based rationale relying on authoritative evidence such as:
  - Studies from government agencies (e.g. the FDA);
  - Evaluations performed by independent technology assessment groups (e.g. BCBSA); and
  - Well-designed controlled clinical studies that have appeared in peer review journals; and
- In providing its justification, the MAO may not use conclusory statements with no accompanying rationale (e.g., “It is our policy to deny coverage for this service.”)

The requirement that an MA plan provide coverage for all Medicare-covered services is not intended to dictate care delivery approaches for a particular service. MA plans may encourage enrollees to see more cost-effective provider types than would be the typical pattern in original Medicare, as long as those providers are licensed and
working within the scope of their licenses and the plan complies with the provider anti-discrimination rules set forth in 42 CFR §422.205.

An MA plan’s flexibility to deliver care using cost-effective approaches should not be construed to mean that Medicare coverage policies do not apply to the MA program. If original Medicare covers a service only when certain conditions are met, then such conditions must be met in order for the service to be considered part of the original Medicare benefits component of an MA plan. An MA plan may cover the same service when the conditions are not met, but these benefits would then be defined as supplemental.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

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MPC Medical Policy Committee

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