

This content has been created to supplement the MCG care guidelines. MCG Health has neither reviewed nor approved the modified material.

** Please note: The Clinical Coverage Guideline (CCG) is intended to supplement certain standard Alignment Health (Alignment) benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific mandates. Information is current at time of approval by the Quality Improvement Committee (QIC) and are subject to change.*

AHC Step Therapy

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MCG Health
Ambulatory Care
28th Edition

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Clinical Indications

The purpose of this policy is to describe the process Alignment Healthcare follows when applying step therapy to certain part B medications. This policy will be reviewed and updated regularly by Alignment Health plan in collaboration with Pharmacy Benefit Management (PBM) as CMS regulations and guidance change, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Step therapy is a type of prior authorization for drugs that begins medication for a medical condition with the most preferred drug therapy and progresses to other therapies only if necessary, promoting better clinical decisions.

CMS determines that the health plan may implement its own step therapy where there is no NCD/LCD. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements.

Step therapy can only be applied to new prescription. Part B beneficiaries who are actively taking the Part B drug are exempt from the step therapy requirement. The CMS final rule implements a 365-daylookback period.

Alignment Health plan step therapy program is approved by PBM's pharmacy and therapeutic (P&T) committee. This P&T committee satisfies CMS requirements in terms of membership. P&T committee review and approve step therapy programs used in connection with Part B drugs.

CMS final rule requires that health plan must respond to a beneficiary's request for coverage, or to an appeal of a denial of such a request, within 24-72 hours. Enrollees must be able to request an exception from the plan's step therapy requirement in order to access a Part B covered drug. CMS considers plan decisions involving requests for exceptions to be pre-service organization determinations (subjected to same timeline and notification requirements)

Per CMS guidance, for Part B step therapy programs beginning in CY2020 and going forward, neither a drug management care coordination program (DM-CCP) or Step Therapy-related incentives are required or "coupled" with the optional Step Therapy program requirements. Alignment health plan will not be offering these programs.

Health plan will be permitted to require an enrollee to try and fail drugs supported only by an off-label indication (an indication only supported in the statutory compendia) before providing access to a drug supported by an FDA approved indication (on-label indication) if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices. Generally, CMS requires such authoritative guidelines to be endorsed or recognized by United States government entities or medical specialty organizations.

As stipulated in 42CFR 422.111(d), Alignment will ensure the list of Part B drugs subject to its Part B Step Therapy will be updated on the website (including the link in the EOCs) a minimum of 30 days prior to implementation of any changes to the list.

Treatment Plan

For updated information on medications subject to step therapy, please go to: Part B Prescription Drugs - Subject to Step Therapy

References

- <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs>
 - <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f>
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Committee Approval

- 01/09/2024, 02/20/2025: Committee approval
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Application

- This policy applies to the following states: Arizona, California, Nevada, North Carolina, and Texas.
 - Please refer to the CMS website for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.
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Policy Revision History

- 12/23/2022: Creation date
 - 12/8/2023: Revision
 - 11/12/2024: Annual review, Applicable states updated, Florida removed
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Codes

HCPCS: J0178, J0179, J0897, J2777, J2778, J2779, J3489, J3590, J7999, J9035, J9311, J9312, Q5115, Q5119, Q5123
