

Priority Health
Medicare Part B

Prior Authorization and Step Therapy Criteria

January 2027

Priority Health

Medicare Part B

Prior Authorization and Step Therapy Criteria

This document contains information regarding Priority Health Medicare Part B (medical) drugs requiring prior authorization and/or step therapy. For medical procedures, refer to the Medicare Coverage Database and Priority Health's Medical Policies for applicable coverage policies.

Priority Health Medicare complies with National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Article (LCA), and other coverage and benefit conditions included in Traditional Medicare law. When such coverage criteria do not exist or are not fully established, Priority Health Medicare may create coverage criteria based on CMS-approved compendium and current evidence in widely used treatment guidelines or clinical literature.

What is a Part B drug?

Outpatient prescription drugs and biologicals eligible for coverage under Medicare Part B. Part B drugs are usually limited to drugs or biologicals administered by infusion or injection furnished incident to a physician or provider service and not usually self-administered by the patient.

What is an NCD, LCD, and LCA?

NCD, LCDs, and LCAs contain coverage criteria set by the Centers of Medicare & Medicaid Services (CMS) or a Medicare Administrative Contractor (MAC) to determine if a drug is reasonable and necessary for the treatment of a condition.

What is a prior authorization?

Prior authorization (PA) means that certain criteria must be met before Priority Health Medicare may approve (cover) the drug. Prior authorization may also be required to determine if the drug is covered under the medical (Medicare Part B) or pharmacy (Medicare Part D) benefit (known as Part B vs Part D) or if a drug is used in a manner that exceeds other coverage limits as referenced on the [Medical Drug List \(MDL\)](#).

What is step therapy?

Step Therapy (ST) means that trying a preferred or more cost-effective drug is required before taking a step up to a drug that is non-preferred. Step therapy for Part B drugs applies to members who are enrolled in a Medicare Advantage Prescription Drug (MAPD) plan and are not currently receiving the Part B drug.

What is a medically accepted indication (MAI)?

Medically accepted indications (MAIs) are defined by the Centers for Medicare and Medicaid Services (CMS) and depend on the benefit (Part D versus Part B) and whether the drug is used in an anti-cancer regimen.

For Part D: Refer to the [Medicare Prescription Drug Benefit Manual Chapter 6, §10.6 – Medically Accepted Indication](#).

For Part B: If no NCD, LCD, LCA or other coverage policies exist, Part B drugs will be reviewed for a medically accepted indication. [Refer to the Medicare Benefit Policy Manual, Chapter 15, §50.4.2 – Unlabeled Use of Drug](#). An unlabeled use of a drug may be covered if a Priority Health Clinical Reviewer or Medical Director determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

How does Priority Health Medicare determine criteria for a Part B drug?

Priority Health Medicare complies with NCDs, LCDs, LCAs, and general coverage and benefit conditions included in Traditional Medicare law. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. When such coverage and benefit criteria do not exist or are not fully established, Priority Health Medicare may create coverage criteria based on CMS-approved compendium and current evidence in widely used treatment guidelines or clinical literature made publicly available to CMS, enrollees, and providers. The coverage criteria are reviewed and approved by Priority Health's Pharmacy and Therapeutics (P&T) Committed prior to implementation (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

How do I know what criteria to use for a Part B drug?

First, check for applicable Medicare NCDs, LCDs, LCAs, and other Medicare guidance using the Medicare Coverage Database at:

<https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>.

Next, check for additional Priority Health Medicare coverage criteria using the [Medical Drug List \(MDL\)](#) and this Priority Health Medicare Part B Prior Authorization and Step Therapy Criteria document. The MDL lists most drugs available under the Part B (medical) benefit and any applicable coverage limits such as PA, ST, and/or Part B vs Part D determinations.

Providers are responsible for reviewing NCDs, LCDs and/or LCAs or other Medicare coverage guidance. Priority Health Medicare attempts to provide as much information as possible; however, if there is a conflict between this document and any Medicare coverage guidance, the Medicare coverage guidance will supersede.

How do I use this criteria document?

This criteria document is meant to be used alongside the [Medical Drug List \(MDL\)](#) with the following prior authorization (PA) forms and websites:

- [Medicare Part B vs Medicare Part D Drug Request form](#) (general form used to request coverage for drugs that may be covered under Part B or Part D. Includes required information necessary for billing purposes.)
- [Medicare Medical \(Part B\) Prior Authorization form](#) (general form used to request coverage for Part B drugs that have PA and/or step therapy (ST). Includes required information necessary for billing purposes.)

- [Oncology Drug Request form](#) (general form used to request coverage for chemotherapeutic (cancer) medications requiring PA and/or ST under Part B. Includes required information necessary for billing purposes.)
- Medicare Coverage Database Search (website to search for National and Local Coverage Determinations and Coverage Articles [NCD, NCA, LCD, and LCAs]: <https://www.cms.gov/medicare-coverage-database/search.aspx>)

Dose, frequency, place of administration and other billing information are required for appropriate billing and coverage of the requested drug(s). Please use the above forms to provide the necessary information and improve the timeliness of the request.

What if my request does not meet criteria and/or is not approved by the FDA?

You can request an exception to the coverage criteria including required indications and FDA-approved dose, frequency and/or route of administration.

Approval for exceptions require supporting evidence (i.e., medical records; medical literature) that demonstrates the exception is medically necessary.

Approval for indications, dosing, or route of administration not approved by the FDA or recognized in Medicare-accepted compendia (e.g., DrugDex, AHFS, Clinical Pharmacology) requires supporting evidence for coverage including published peer-reviewed literature supporting the appropriateness of the drug, the dose, and/or route of administration for the requested indication.

What if I cannot find my drug on the Medical Drug List (MDL) or this Prior Authorization/StepTherapy document?

Most drugs in this document are listed in alphabetical order according to their trade name unless the drug is available generically in which the drug will be listed by its generic name. Occasionally, when two or more drugs used to treat the same condition have the same coverage criteria, these may be grouped into one listing (e.g., botulinum toxins).

For new-to-market drugs not yet reviewed by the Priority Health Pharmacy and Therapeutics (P&T) Committee, the following criteria are required:

1. Use of the drug for a Medically Accepted Indication – and –
2. Use of all appropriate alternative covered Part D drugs (for plans with prescription drug coverage) and Part B drugs with evidence-based support for the requested indication

For other Part B drugs not found, use the Medicare Coverage Database tool at <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx> to review for applicable coverage policies (i.e., NCDs, LCDs or LCAs).

References & Summary of Evidence

For Medicare Part B Prior Authorization and Step Therapy

Priority Health Medicare complies with National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Article (LCA), and other coverage and benefit conditions included in Traditional Medicare law for Part B drugs. These resources contain coverage criteria set by the Centers of Medicare & Medicaid Services (CMS) or a Medicare Administrative Contractor (MAC) to determine if a drug is reasonable and necessary for the treatment of a condition.

When coverage criteria do not exist or are not fully established in an NCD, LCD/LCA, or other Medicare statute or regulation, Priority Health Medicare may create internal coverage criteria based on CMS-approved compendium and current evidence in widely used treatment guidelines or clinical literature.

In accordance with Medicare law, when internal coverage criteria are created, Priority Health provides a publicly accessible summary of evidence considered during the development of the internal coverage criteria, a list of the sources of such evidence, and an explanation of the rationale supporting the adoption of the internal coverage criteria. This document presents this information.

A Medicare Administrative Contractor (MAC) establishes LCDs for Medicare Part A and Part B (A/B) medical drugs and services and Medicare Durable Medical Equipment (DME) for defined geographic areas or jurisdictions. Michigan falls under A/B MAC Jurisdiction 8 and DME MAC Jurisdiction B. For more information on NCDs, MACs, and LCDs/LCAs, refer to the Medicare Benefit Policy Manual, Chapter 15, [CMS.GOV](https://www.cms.gov), and the [Medicare Coverage Database](#).

