Reference number(s)
5606-A

Standard Medicare Part B Management Universal Criteria for Medicare Part B

Program Summary

The Universal Criteria for Medicare Part B ensure appropriate utilization of medications eligible for reimbursement under Medicare Part B and confirm that selection elements established in the FDA-approved product labeling and Medicare-approved compendia are followed. These universal criteria for approval apply to medications not otherwise managed through a product-specific Medicare Part B program. The criteria may be applied in situations where specific criteria are pending development.

These universal criteria confirm the medication is prescribed for an FDA-approved indication or other indications supported by Medicare and that the member has no contraindications to therapy as described in the FDA-approved product labeling.

Exclusions

Coverage will not be provided for members with any of the following exclusions:

- Medications given for a purpose other than the treatment of a particular condition, illness, or injury. Charges for medications (e.g., vitamins) given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage.
- The requested medication will be given by injection (parenterally) and standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.
- Medication administered for treatment of a disease which exceed the frequency or duration of injections indicated by accepted standards of medical practice.

Coverage Criteria

Authorization of 12 months may be granted for a requested medication when all of the following criteria are met:

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- The requested drug can be covered under Medicare Part B based on one of the following criteria:
    - The requested drug is not usually self-administered and will be furnished by the physician and administered by the physician or by auxiliary personnel employed by the physician and under the physician's supervision.
    - The requested drug, including those which may be considered usually self-administered, is being provided as an integral component of a procedure or is directly related to it (i.e., they facilitate the performance of or recovery from a particular procedure).
    - The requested drug is used as a service or supply (including drugs and biologicals which are not usually self-administered) that is furnished incident to a physician's or other practitioner's services, that is commonly included in the physician's or practitioner's bills and the payment is not made under a separate benefit category and all of the following apply:
        - The requested drug is an integral, although incidental, part of the physician's professional service in the course of diagnosis or treatment of an injury or illness.
        - The requested drug is commonly rendered without charge or included in the physician's bill.
        - The requested drug is of a type that is commonly furnished in physician's offices or clinics.
        - The requested drug is furnished by the physician or by auxiliary personnel under the physician's direct supervision.
    - The requested drug requires administration by the use of a piece of covered durable medical equipment (DME) such as a nebulizer, external or implantable pump.
    - The requested drug is used for immunosuppressive therapy and meets all of the following:
        - It is approved for marketing by the FDA and meets one of the following:
            - The approved labeling includes an indication for preventing or treating the rejection of a transplanted organ or tissue.
            - The approved labeling includes the indication for use in conjunction with immunosuppressive drugs to prevent or treat rejection of a transplanted organ or tissue.
            - The DME MAC has determined it is reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, or for use in conjunction with immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue.

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- If the requested drug is a compounded formulation, it is orally or enterally administered.

- The requested drug is a hemophilia clotting factor for hemophilia patients with Factor VIII deficiency (classic hemophilia), Factor IX deficiency (plasma thromboplastin component [PTC] or Christmas factor deficiency) or Von Willebrand's disease who are competent to use such factors to control bleeding without medical supervision.
- The requested drug is prescribed as an oral anti-cancer agent and all of the following apply:
    - The requested drug is being prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents.
    - The requested drug or biological has been approved by the FDA.
    - The requested drug has the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service.
    - The requested drug and the non-self administrable drug have the same chemical/generic name as indicated by the FDA's "Approved Drug Products" (Orange Book), "Physician's Desk Reference" (PDR), or an authoritative drug compendium.
    - The requested drug is being used for the same indications, including unlabeled uses, as the non-self administrable version of the drug.
    - The requested drug is reasonable and necessary for the individual patient.
- The requested drug is an oral antiemetic (anti-nausea) drug being used as full replacement for intravenous dosage forms of a cancer regimen and all of the following apply:
    - The requested oral drug is approved by the FDA for use as an anti-emetic.
    - The requested drug is being administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen.
    - Treatment is initiated within 2 hours of the administration of the chemotherapeutic agent when administered with a particular chemotherapy treatment, and is continued for a period not to exceed 48 hours from that time.
    - The requested oral drug is being used as a full therapeutic replacement for the intravenous anti-emetic drug that would have otherwise been administered at the time of the chemotherapy treatment.
- The requested drug is a vaccination or inoculation being used directly related to the treatment of an injury or direct exposure to a disease or condition (e.g., anti-rabies

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treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin).

- The requested drug is the pneumococcal vaccine.
- The requested drug is the hepatitis B vaccine, and the member is at high or intermediate risk of contracting hepatitis B.
- The requested drug is the influenza vaccine.
- The requested drug is the COVID-19 vaccine.
- The requested drug is an antigen prepared by a physician who is a doctor of medicine or osteopathy for a specific patient and the physician who prepares the antigen has examined the patient and has determined a plan of treatment and a dosage regimen.
- The requested drug is used for parenteral nutrition to supply nutrients to a beneficiary who cannot absorb nutrition through their intestinal tract.
- The requested drug is used for end stage renal disease (ESRD) beneficiaries receiving renal dialysis services and will be submitted as part of the Medicare Part B bundled payment to an ESRD dialysis facility.
- The requested drug is an intravenous immune globulin (IVIG) provided in the home for members with a diagnosis of primary immune deficiency disease and a physician has determined that the administration of the IVIG in the patient's home is medically appropriate.
- The requested drug is Epoetin Alfa (Procrit) for preoperative use to reduce the risk of transfusion when all of the following are met:
    - The patient is undergoing hip or knee surgery.
    - The patient has anemia with a hemoglobin between 10 and 13 mg/dL.
    - The patient is not a candidate for autologous blood transfusion.
    - The patient is expected to lose more than 2 units of blood.
    - The patient had a workup so that their anemia appears to be that of chronic disease.
    - The requested drug is determined to be reasonable and necessary.

- The requested drug being prescribed is safe and effective and otherwise reasonable and necessary as defined by one of the following:
    - The requested drug is prescribed for an FDA-approved indication.
    - The requested drug is prescribed for anticancer chemotherapy and the indication is supported by the one of the following:
        - The indication is listed in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with NCCN Category of 1 or 2A.
        - The indication is listed in Micromedex DrugDex with recommendation level of I, IIa, or IIb.

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- The indication is listed in the American Hospital Formulary Service Drug Information reference (AHFS-DI) with “supportive” narrative text.
- The indication is listed in Clinical Pharmacology with “supportive” narrative text.
- The indication is listed in Lexi-Drugs as “Use: Off-Label” and rated as “Evidence Level A”.
- The indication is supported by peer-reviewed published medical literature appearing in the regular editions of one of the following publications:
    - American Journal of Medicine.
    - Annals of Internal Medicine.
    - Annals of Oncology.
    - Annals of Surgical Oncology.
    - Biology of Blood and Marrow Transplantation.
    - Blood.
    - Bone Marrow Transplantation.
    - British Journal of Cancer.
    - British Journal of Hematology.
    - British Medical Journal.
    - Cancer.
    - Clinical Cancer Research.
    - Drugs.
    - European Journal of Cancer.
    - Gynecologic Oncology.
    - International Journal of Radiation, Oncology, Biology, and Physics.
    - The Journal of the American Medical Association.
    - Journal of Clinical Oncology.
    - Journal of the National Cancer Institute.
    - Journal of the National Comprehensive Cancer Network (NCCN).
    - Journal of Urology.
    - Lancet.
    - Lancet Oncology.
    - Leukemia.
    - The New England Journal of Medicine.
    - Radiation Oncology.
- The off-label use is supported by clinical research, which is considered peer-reviewed medical literature that appears in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only

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after having been critically reviewed for scientific accuracy, validity and reliability by unbiased, independent experts prior to publication.

  - The requested drug is prescribed for a use other than anticancer chemotherapy and the indication is determined to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.
- The member does not have contraindications to therapy as described in the prescribing information.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The Medicare Benefit Policy Manual, Chapter 15 (Covered Medical and Other Health Services)
- The Medicare Prescription Drug Benefit Manual, Chapter 6 (Part D Drugs and Formulary Requirements)
- Applicable regulations, including Part 422- Medicare Advantage Program, Section 422.101 (Requirements relating to basic benefits).

Explanation of Rationale

The exclusions listed within this criteria can be found in the Medicare Benefit Policy Manual, Chapter 15, section 50.4.3 (Examples of Not Reasonable and Necessary).

Support for FDA-approved indications can be found in the package insert for the requested drug.

Support for services or supplies can be found in Chapter 15, section 60.

Support for the use of the requested drug in an anti-cancer chemotherapeutic regimen can be found in the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen). The approved compendium and level of evidence are as follows:

- Indication is listed as a Category 1 or 2A in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Indication is listed as Class I, Class IIa, or Class IIb in Micromedex DrugDex database.
- Narrative text in the American Hospital Formulary Service- Drug Information database is supportive.
- Narrative text in the Clinical Pharmacology database is supportive.
- Indication is listed in the Lexi-Drugs database as “use: off-label” and rated as “Evidence Level A”

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Additionally, the Medicare Benefit Policy Manual, Chapter 15 lists several acceptable peer-reviewed medical journals. The expectation is the reviewer will evaluate the study and consider (among other things) the following:

- Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
- Whether the administered chemotherapy regimen is adequately represented in the published evidence
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
- Whether the study is appropriate to address the clinical question. The following should be considered:
    - Whether the experimental design is appropriate to address the investigative question
    - Non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
    - Case reports are generally uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Finally, support for use of the requested drug for anticancer chemotherapy can be found in section 422.101(b)(6). The regulation states Medicare Advantage organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs, or LCDs. Support can be found by clinical research which is considered peer-reviewed medical literature that appears in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity and reliability by unbiased, independent experts prior to publications according to Chapter 15 Section 50.4.2.

Support for use of the requested drug for an indication other than as part of an anti-cancer chemotherapeutic regimen can be found in section 422.101(b)(6). The regulation states Medicare Advantage organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs, or LCDs. Support can be found in Chapter 15, Section 50.4.2 for off label uses determined to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice.

Support for use with ESRD for those receiving renal dialysis services being submitted as part of the Medicare Part B bundled payment to an ESRD dialysis facility is found within Chapter 6, section 20.2.

Support for use of drugs administered by durable medical equipment (DME) is found within Chapter 6, Appendix C.

Support for all other covered indications can be found in Chapter 15 and Chapter 6.

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Contraindications are conditions under which the drug or device should not be used because the risk of use clearly outweighs any possible benefit. The inclusion of contraindication in the above policy outweighs any clinical harms, including from delayed or decreased access to items or services.

References

1. Centers for Medicare and Medicaid Services: CMS Benefit Policy Manual Chapter 15- Covered Medical and Other Health Services. https://www.cms.gov/medicare/prevention/prevntiongeninfo/downloads/bp102c15.pdf Accessed March 12, 2026.
2. Centers for Medicare and Medicaid Services: Medicare Prescription Drugn Benefit Manual Chapter 6- Part D Drugs and Formulary Requirements. https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf. Accessed February 11, 2026.
3. Centers for Medicare and Medicaid Services: Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.
4. Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products-Content and Format. Food and Drug Administration. https://www.fda.gov/media/71866/download Accessed February 13, 2026.

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