Reference number(s)
5606-A

STANDARD MEDICARE PART B MANAGEMENT

UNIVERSAL CRITERIA FOR MEDICARE PART B

POLICY

I. 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.

II. EXCLUSIONS

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

A. Medications not 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.
B. The requested medication will be given by injection and standard medical practice indicates that the administration of the medication by mouth is effective and is an accepted or preferred method of administration.
C. Medication administered for treatment of a disease which exceed the frequency or duration of injections indicated by accepted standards of medical practice.

III. CRITERIA FOR APPROVAL

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

A. The medication can be covered under Medicare Part B based on one of the following criteria:
    1. The injection is not usually self-administered and will by furnished by the physician and administered by the physician or by auxiliary personal employed by the physician and under the physician's supervision.
    2. The medication requires administration by the use of a piece of covered durable medical equipment (DME) such as a nebulizer, external or implantable pump.
    3. The medication is used in immunosuppressive therapy for a beneficiary who has received a Medicare covered organ transplant.
    4. The medication is a hemophilia clotting factor for hemophilia patients competent to use such factors to control bleeding without medical supervision.

5. The medication is taken orally during cancer chemotherapy provided it has the same active ingredient and are used for the same indications as chemotherapy drugs that would be covered if they were not self-administered and were administered as incident to a physician's professional service.
6. The medication is an oral antiemetic (anti-nausea) drug used as part of an anti-cancer chemotherapeutic regimen as full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration.
7. The requested drug is the pneumococcal vaccine ordered by a physician.
8. The requested drug is the hepatitis B vaccine, and the member is at high or intermediate risk of contracting hepatitis B.
9. The requested drug is the influenza vaccine.
10. The requested drug is an antigen prepared by a physician for a specific patient.
11. The requested drug is used for parenteral nutrition to supply nutrients to a beneficiary who cannot absorb nutrition through their intestinal tract.

B. The medication is being prescribed for one of the below indications:
1. The medication is prescribed for an FDA-approved indication.
2. The medication is prescribed for anticancer chemotherapy and the indication is supported by the one of the following:
   i. The indication is listed in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with NCCN Category of 1 or 2A.
   ii. The indication is listed in DrugDex with recommendation level of I, IIa, or IIb.
   iii. The indication is listed in the American Hospital Formulary Service Drug Information reference (AHFS-DI) with "supportive" narrative text.
   iv. The indication is listed in Clinical Pharmacology with "supportive" narrative text.
   v. The indication is listed in Lexi-Drugs as "Use: off-label" and rated as "Evidence Level A".
   vi. The indication is supported by peer-reviewed published medical literature in one of the following publications:
      a. American Journal of Medicine
      b. Annals of Internal Medicine
      c. Annals of Oncology
      d. Annals of Surgical Oncology
      e. Biology of Blood and Marrow Transplantation
      f. Blood
      g. Bone Marrow Transplantation
      h. British Journal of Cancer
      i. British Journal of Hematology
      j. British Medical Journal
      k. Cancer
      l. Clinical Cancer Research
      m. Drugs
      n. European Journal of Cancer
      o. Gynecologic Oncology
      p. International Journal of Radiation, Oncology, Biology, and Physics
      q. The Journal of the American Medical Association
      r. Journal of Clinical Oncology
      s. Journal of the National Cancer Institute
      t. Journal of the National Comprehensive Cancer Network (NCCN)
      u. Journal of Urology
      v. Lancet
      w. Lancet Oncology
      x. Leukemia
      y. The New England Journal of Medicine
      z. Radiation Oncology

vii. The indication is supported by widely used treatment guidelines, such as those developed by organizations representing clinical medical specialties.
viii. The indication is supported by one or more large, randomized controlled trials or cohort studies or all-or-none studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question.
ix. The indication is supported by one or more large systematic reviews or meta-analyses summarizing the literature of the specific clinical question published in a peer-reviewed journal with clear and consistent results.

3. The medication is prescribed for a use other than anticancer chemotherapy and the indication is supported by one of the following:
   i. The indication is supported by widely used treatment guidelines, such as those developed by organizations representing clinical medical specialties
   ii. The indication is supported by one or more large, randomized controlled trials or cohort studies or all-or-none studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question.
   iii. The indication is supported by one or more large systematic reviews or meta-analyses summarizing the literature of the specific clinical question published in a peer-reviewed journal with clear and consistent results.

C. The member does not have contraindications to therapy as described in the prescribing information.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The Medicare Benefit Policy Manual, Chapter 15 (Covered Medical and Other Health Services)
2. The Medicare Prescription Drug Benefit Manual, Chapter 6 (Part D Drugs and Formulary Requirements)
3. Applicable regulations, including Part 422- Medicare Advantage Program, Section 422.101 (Requirements relating to basic benefits).

V. EXPLANATION OF RATIONALE

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

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:
1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence

3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question. The following should be considered
   a. Whether the experimental design is appropriate to address the investigative question
   b. Non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs
   c. 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. Current, widely-used treatment guidelines are those developed by organizations representing medical specialties and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

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. Current, widely-used treatment guidelines are those developed by organizations representing medical specialties and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

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.

VI. REFERENCES

1. Centers for Medicare and Medicaid Services: CMS Benefit Policy Manual Chapter 15- Covered Medical and Other Health Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf Accessed February 23, 2023.
2. Centers for Medicare and Medicaid Services: Medicare Prescription Drug 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 23, 2023.
3. Centers for Medicare and Medicaid Services: Contract Year 2024 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 May 31, 2023.