**Oncology**

## 1. MCG Criteria Used

**Clinical Criteria: MCG Care Guidelines, 30th Edition**

- Chemotherapy: Inpatient Admission (MCG ORG: M-87 ISC, 30th Edition)
- Bevacizumab (MCG ORG: A-0491 AC, 30th Edition)

**Applicable CPT / HCPCS Codes:**

| CPT / HCPCS Code | Description |
|---|---|
| **96401, 96402** | Chemotherapy administration, subcutaneous or intramuscular; non-hormonal or hormonal anti-neoplastic |
| **96409, 96411** | Chemotherapy administration, intravenous push technique; single or each additional substance/drug |
| **96413, 96415-96417** | Chemotherapy administration, intravenous infusion; up to 1 hour, each additional hour, and each additional sequential infusion |
| **96420-96425** | Chemotherapy administration, intra-arterial; push or infusion technique |
| **38225-38228** | CAR-T cell therapy and related cellular immunotherapy administration |
| **J9035** | Injection, bevacizumab, 10 mg (HCPCS drug code) |
| **C9257** | Injection, bevacizumab, 0.25 mg (hospital outpatient, ophthalmic use) |
| **Q5129** | Injection, bevacizumab biosimilar, per qualifying dose (HCPCS) |

## 2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding oncology services, including inpatient admission for the administration of chemotherapy, immunotherapy, or targeted therapy requiring inpatient support, and the administration of bevacizumab for its approved oncologic and ophthalmic indications, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of oncology services and to determine when such services are medically necessary.

Cancer treatment in the Medicare Advantage population spans high-acuity inpatient chemotherapy with significant expected toxicity through ambulatory administration of targeted biologic agents such as bevacizumab. Each carries distinct clinical stakes: undertreatment risks cancer progression and treatment failure, while inpatient cytotoxic therapy and antiangiogenic agents carry serious toxicity that requires appropriate setting and monitoring. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary cancer treatment and inappropriate approval of high-acuity or high-cost therapy outside its supported indications or setting.

**Potential Clinical Harms:**

**Chemotherapy inpatient admission:** Inappropriate denial of inpatient admission for chemotherapy, immunotherapy, or targeted therapy that requires inpatient support, that carries expected toxicity requiring inpatient care, or that has produced complications requiring inpatient care could result in administration of high-risk regimens without the monitoring and supportive care needed to manage tumor lysis syndrome, cytokine release syndrome, febrile neutropenia, severe cytopenias, and other life-threatening toxicities. Premature discharge or denial of admission in these circumstances increases the risk of preventable morbidity and mortality.

**Bevacizumab:** Inappropriate denial of bevacizumab for an approved oncologic indication (e.g., metastatic colorectal cancer, non-small cell lung cancer, ovarian or cervical cancer, hepatocellular carcinoma, malignant glioma, renal cancer, mesothelioma) could deny patients an evidence-based antiangiogenic therapy and allow disease progression. Inappropriate denial for an approved intravitreal indication (e.g., diabetic macular edema, neovascular age-related macular degeneration, macular edema following retinal vein occlusion, myopic choroidal neovascularization) could allow progression of vision-threatening retinal disease to permanent vision loss.

**Clinical Benefits:**

**Chemotherapy inpatient admission:** MCG criteria provide validated indications for inpatient admission tied to the need for inpatient support, expected toxicity, and management of complications, drawn from oncology evidence and specialty guidance. By tying admission to these specific clinical factors, the criteria directly counter the harm of unmonitored high-toxicity therapy identified above while supporting appropriate level of care with a goal length of stay of 3 days; analysis of national hospital discharge data shows 37% of chemotherapy-related encounters were discharged in 3 days or less, supporting the goal length of stay.

**Bevacizumab:** MCG criteria specify the approved oncologic and intravitreal indications for bevacizumab and tie each to clinical evidence. For diabetic macular edema, evidence demonstrates at least moderate certainty of at least moderate net benefit, with meta-analyses and systematic reviews and a randomized trial (Jhaveri 2022) supporting vascular endothelial growth factor inhibition. For the oncologic indications, the criteria require age 18 or older, a malignancy appropriate for bevacizumab, and absence of contraindications such as central nervous system metastasis where applicable, reserving therapy for evidence-supported uses. This directly addresses the harm of denied evidence-based cancer and retinal therapy identified above.

**Reduction of unwarranted variation and overutilization:** MCG criteria identify when observation care is appropriate rather than inpatient admission for lower-acuity chemotherapy, and require the specific prerequisite findings for each bevacizumab indication, reducing unnecessary inpatient exposure and non-indicated biologic therapy. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current oncology and ophthalmology specialty society guidelines and high-quality evidence, including numerous Cochrane systematic reviews. Use of these criteria ensures patients receive the most clinically appropriate care, and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

## 3. Explanation of Supplementation

**Basis for Use:**

Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for specific oncology services, including inpatient admission for chemotherapy and the administration of bevacizumab. While Medicare statutes

establish the general 'reasonable and necessary' standard, they do not specify the clinical thresholds (e.g., the inpatient-support, toxicity, and complication criteria for chemotherapy admission, or the indication-specific prerequisites for bevacizumab) required to distinguish inpatient-appropriate from observation-appropriate care and indicated from nonindicated therapy.

**Applicable Medicare References:**

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard
- Medicare Benefit Policy Manual, Chapter 1: Inpatient Hospital Services Covered Under Part A (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (CMS IOM Publication 100-02)
- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: For inpatient chemotherapy admission and bevacizumab administration, no specific NCD or LCD fully establishes clinical thresholds; Original Medicare criteria are not fully established for these services, requiring supplementation. Where applicable LCDs address chemotherapy or bevacizumab, MCG criteria are used to supplement and do not replace them.
- Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/search.aspx

Within the above statutes and regulations, coverage criteria for these specific oncology services are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of inpatient admission for chemotherapy, immunotherapy, or targeted therapy requiring inpatient support, carrying expected toxicity, or producing complications requiring inpatient care, versus observation or outpatient administration;
- Medical necessity and appropriateness of bevacizumab for its approved oncologic indications and approved intravitreal indications, including the prerequisite clinical findings for each;
- Appropriate level of care, expected clinical course, and identification of complications that warrant inpatient admission or stay extension during cancer treatment.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of oncology services. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure cancer treatment is not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

## 4. Summary of Clinical Evidence

## Background

### Chemotherapy: Inpatient Admission (MCG ORG: M-87 ISC)

Inpatient admission for chemotherapy addresses the administration of chemotherapy, immunotherapy, or targeted therapy that requires inpatient support, that carries expected toxicity requiring inpatient care, or that has produced complications requiring inpatient care. The guideline carries a goal length of stay of 3 days postadmission and recognizes observation care as an alternative for appropriate lower-acuity presentations.

### Bevacizumab (MCG ORG: A-0491 AC)

Bevacizumab is a vascular endothelial growth factor inhibitor administered either intravitreally for retinal conditions or systemically for malignancy. Intravitreal indications include diabetic macular edema, macular edema following retinal vein occlusion, myopic choroidal neovascularization, neovascular age-related macular degeneration, and ocular histoplasmosis with choroidal neovascularization, requiring age 18 or older and absence of concurrent ocular or periocular infection. Systemic oncologic indications include cervical cancer, metastatic colorectal cancer, hepatocellular carcinoma, malignant glioma, mesothelioma, non-small cell lung cancer, ovarian/fallopian tube/primary peritoneal cancer, and renal carcinoma, each with its own prerequisite criteria. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

## Evidence Summary

### Chemotherapy: Inpatient Admission (MCG ORG: M-87 ISC)

The evidence for the clinical indications in this guideline includes 56 published peer-reviewed articles, 1 specialty society or other evidence-based guideline, and 6 book sections. Key evidence includes:

- Analysis of national hospital discharge data for a commercially insured population shows 67.5% of patients seen in an emergency department with a principal diagnosis related to chemotherapy were admitted to inpatient care, reflecting the high acuity of chemotherapy-related presentations.
- The criteria support inpatient admission when chemotherapy, immunotherapy, or targeted therapy requires inpatient support, carries expected toxicity requiring inpatient care, or has produced complications requiring inpatient management.
- Analysis of national hospital discharge data shows 37% of hospitalized adult patients with chemotherapy-related encounters as the principal diagnosis were discharged in 3 days or less, supporting the MCG goal length of stay of 3 days.

### Bevacizumab (MCG ORG: A-0491 AC)

The evidence for the clinical indications in this guideline includes 149 published peer-reviewed articles, 17 specialty society or other evidence-based guidelines, and 13 Cochrane systematic reviews. Key evidence includes:

- For diabetic macular edema, evidence demonstrates at least moderate certainty of at least moderate net benefit. Meta-analyses and systematic reviews demonstrate that vascular endothelial growth factor inhibitors are active against diabetic macular edema, with comparative trial evidence (Jhaveri 2022) informing the role of bevacizumab relative to other agents.
- For neovascular age-related macular degeneration, macular edema following retinal vein occlusion, and myopic choroidal neovascularization, specialty society guidance and trial evidence support intravitreal bevacizumab as an effective antiangiogenic therapy.
- For the systemic oncologic indications, specialty society guidelines support bevacizumab in combination regimens for metastatic colorectal cancer, non-small cell lung cancer, ovarian/fallopian tube/primary peritoneal cancer, cervical cancer, hepatocellular carcinoma,

malignant glioma, mesothelioma, and renal carcinoma, with the criteria requiring the appropriate malignancy and absence of contraindications.

**Rationale (from MCG)**

Use of these MCG care guidelines helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate setting for oncology services. For the chemotherapy guideline, the evidence-based clinical criteria assist the clinician in deciding when inpatient admission is appropriate based on the need for inpatient support, expected toxicity, and complications, including identification of complex factors that make it reasonable to expect a necessity for hospital care across 2 or more midnights and CMS Two-Midnight Rule exceptions for Medicare enrollees. For the bevacizumab guideline, the criteria help the clinician decide when the agent is appropriate for a specific approved indication based on prerequisite clinical findings. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

**Related CMS Coverage Guidance (as cited in MCG 30th Edition):**

- Code of Federal Regulations (CFR): 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101 (chemotherapy inpatient admission); 42 CFR 419.22; 42 CFR 422.101 (bevacizumab)
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 1 (Inpatient Hospital Services); Chapter 6 (Hospital Services Under Part B); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5
- Medicare Coverage Determinations: Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/search.aspx

**References with Citation Summary -- Chemotherapy: Inpatient Admission (MCG ORG: M-87 ISC, 30th Edition)**

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