AETNA BETTER HEALTH® of Illinois Policy

Policy Name:	Drug and Biological Policy	Page:	1 of 7
Department:	Medical Payment Policy	Policy Number:	XXXX.XX
Subsection:		Effective Date:	10/1/2024
Applies to:	■ Medicaid Health Plans		

PURPOSE: Provide guidance on NDC coding and coverage guidelines for Infliximab, Bevacizumab and Etelcalcetide.

STATEMENT OF OBJECTIVE: The policies are based on the FDA-approved package insert/prescribing information and Illinois State Medicaid Guidelines,

DEFINITIONS:

Aetna Better Health of Illinois	A subsidiary of CVS Health Corporation, Medicaid subsidiary that provides plan management and other administrative services for the Illinois Medicaid program.
The American Medical Association (AMA)	A professional group that publishes research to advance public health and advocates for the interests of registered physician-members.
Current Procedural Terminology (CPT)	A medical code set maintained by the American Medical Association through the CPT Editorial Panel. The CPT code set (copyright protected by the AMA) describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes.
Healthcare Common Procedure Coding System (HCPCS)	Level II of the HCPCS is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. Because Medicare and other insurers cover a variety of services, supplies, and equipment that are not identified by CPT codes, the level II HCPCS codes were established for submitting claims for these items.
Illinois Department of Health Care and Family Services (HFS)	The Department of Healthcare and Family Services administers health insurance programs for children, pregnant women, and adults who are residents of Illinois.
Medicare (CMS)	Medicare is a health insurance program for: people age sixty-five (65) or older, people under age sixty-five (65) with certain disabilities, and

	people of all ages with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant).
Drug and Biological Policy	Established rules, procedures, and criteria set by regulatory and admirative bodies for the approval, manufacturing, coverage, and payment of pharmaceutical drugs and biological products.
National Drug Code (NDC)	A universal, 10 or 11 digit identifier for drugs and biologicals in the U.S., mandated by the FDA.
Bevacizumab	A monoclonal antibody medication used to treat certain types of cancer, by blocking growth of new blood vessels that are needed for tumors to survive and spread.
Etelcalcetide	An IV administered, calcimimetic drug used to treat secondary hyperparathyroidism (SHPT) in adults with chronic kidney disease (CKD) on hemodialysis, by activating the calcium-sensing receptor (CaSR) on parathyroid glands to reduce the secretion of parathyroid hormone (PTH)
Infliximab	A medication that is specifically a chimeric monoclonal antibody, that targets and blocks the effect of tumor necrosis factor-alpha (TNF-α), a protein involved in inflammation.

REIMBURSEMENT GUIDELINES:

National Drug Code (NDC)

- According to our policy, which is based on Food and Drug Administration (FDA) Policy, providers are required to report valid National Drug Code (NDC) numbers and the NDC number should be valid, active, for an approved drug and the HCPCS code and the NDC code should indicate the same drug.

- Aetna Medicaid supports FDA label, off-label compendia (Micromedex, Clinical Pharmacology, National Comprehensive Cancer Network, Lexi-Drugs, American Hospital Formulary Service Drug Information®), AMA/ CPT, state Medicaid guidelines and other sources for Drugs and Biologicals. These supported policies include:

- Indication (FDA-label and off-label approved compendia indications)

- Dosage (based on indication and supported by FDA-label and off-label approved compendia)
- Frequency (based on indication and supported by FDA-label and off-label approved compendia)
- Route of administration (based on category of drug, FDA-label, off-label approved compendia, and AMA/CPT guidelines)
- Age restrictions
- Combination therapy with other required drugs/substances (based on FDA-label and approved off-label compendia guidelines by indication)

Effective 6/1/2025 Infliximab (J1745, Q5103, Q5104, Q5121)
Drugs and Biologicals Policies:

- Aetna Medicaid supports FDA label, off-label compendia (Micromedex, Clinical Pharmacology, National Comprehensive Cancer Network, Lexi-Drugs, American Hospital Formulary Service Drug Information®), AMA/ CPT, state Medicaid guidelines and other sources for Drugs and Biologicals. These supported policies include:

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- -Route of administration (based on category of drug, FDA-label, off-label approved compendia, and AMA/CPT guidelines)
- -Age restrictions
- -Combination therapy with other required drugs/substances (based on FDA-label and approved off-label compendia guidelines by indication)

<u>New Drug/Biological Policies</u>
Infliximab (J1745, Q5103, Q5104, Q5121)

<u>New policies for Infliximab:</u>

- Daily limits added when the diagnosis on the claim is plaque psoriasis (pediatric), pustular psoriasis, or regional enteritis (pediatric).
- Limits over time added when the diagnosis on the claim is plaque psoriasis (pediatric) or regional enteritis (pediatric)
- Daily limits added when the diagnosis on the claim is ulcerative colitis (adult).
- Limits over time added when the diagnosis on the claim is ulcerative colitis (adult).

- Limit number of visits over time allowed when the diagnosis on the claim is ulcerative colitis (adult)

Medicaid - Illinois State Policy-Drug and Biological Policy – Bevacizumab (J9035, Q5107, Q5118, Q5126, Q5129 – Post Major Surgery

The new policies will define guideline requirements for the following:

- J9035 (INJECTION, BEVACIZUMAB, 10 MG)
- Q5107 (INJECTION, BEVACIZUMAB-AWWB, BIOSIMILAR, (MVASI), 10 MG)
- Q5118 (INJECTION, BEVACIZUMAB-BVZR, BIOSIMILAR, (ZIRABEV), 10 MG)
- Q5126 (INJECTION, BEVACIZUMAB-MALY, BIOSIMILAR, (ALYMSYS), 10 MG)
- Q5129 (INJECTION, BEVACIZUMAB-ADCD (VEGZELMA), BIOSIMILAR, 10 MG)

- According to our policy, which is based on the FDA-approved package insert/prescribing information and Illinois Medicaid Policy, bevacizumab should not be initiated for at least 28 days after major surgery and until the surgical wound is fully healed.
- The billed bevacizumab HCPCS code will be denied when reported within 27 days of major surgery.

Medicaid - Illinois State Policy-Drug and Biological Policy – Bevacizumab (J9035, Q5107, Q5118, Q5126, Q5129 – Pre-Major Surgery

The new policies will define guideline requirements for the following:

- J9035 (INJECTION, BEVACIZUMAB, 10 MG)
- Q5107 (INJECTION, BEVACIZUMAB-AWWB, BIOSIMILAR, (MVASI), 10 MG)

- Q5118 (INJECTION, BEVACIZUMAB-BVZR, BIOSIMILAR, (ZIRABEV), 10 MG)
- Q5126 (INJECTION, BEVACIZUMAB-MALY, BIOSIMILAR, (ALYMSYS), 10 MG)
- Q5129 (INJECTION, BEVACIZUMAB-ADCD (VEGZELMA), BIOSIMILAR, 10 MG)

- According to our policy, which is based on the FDA-approved package insert/prescribing information and Illinois State Medicaid Guidelines, bevacizumab should be discontinued at least 28 days prior to elective surgery.

Drug and Biological Policy – Etelcalcetide (J0606)

- According to our policy, which is based on the FDA-approved package insert/prescribing information, when etelcalcetide is used for the reported condition, serum calcium testing must be performed approximately monthly. Patients without serum calcium testing are not eligible for treatment with etelcalcetide.

- The billed etelcalcetide HCPCS code will be denied when billed and the diagnosis on the claim is secondary hyperparathyroidism in adult patients with chronic kidney disease on hemodialysis and serum calcium testing has not been billed for the same date of service or within the previous 34 days by any provider.

LEGAL/CONTRACT REFERENCE:

- Federal and state laws, rules, and regulations concerning the practice of pharmacy, third party administration, Medicaid laws, rules, and regulations
- Applicable federal and state laws, regulations, and directives regarding the confidentiality of member information (e.g., Health Insurance Portability and Accountability Act [HIPAA])

FOCUS/DISPOSITION:

Responsibilities

The chief medical officer (CMO) and chief operating officer (COO) are responsible for review and implementation based upon state and federal regulation. Aetna Medicaid Administrators LLC applies editing rules as implemented by NCCI and AMA standards. Editing may also be developed based upon recommendations for specialty societies.

OPERATING PROTOCOL:

Systems

- Business application systems

Measurement

- Edit Accuracy
- Edit Application
- Overturn of Adjustment Rates

Reporting

- Aetna Medicaid - Cotiviti Healthcare Monthly Performance Summary to plan leadership
- Claim Check Monthly Summary to health plans

INTER-/INTRADEPENDENCIES:

Internal

- Medical Payment Policy
- Payment Integrity Center of Excellence, Service Operations (PIAB)
- Chief Medical Officer

- Chief Operating Officer
- Claims
- Finance
- Medical Management
- Special Investigations Unit

External

- Clinical Editing Vendors
- Practitioners
- Providers
- Regulatory Departments
- Vendors
- Aetna Better Health

Kimberly Foltz
Interim Chief Executive Officer

Glen Davis, MD
Chief Medical Officer

Review/Revision History	
Revised	08/25/2025