Medical Policy

Blue Care Network of Michigan

A nonprofit corporation and independent licensee of the Blue Cross and Blue Shield Association

BCN Medical Policies are a source for BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information.

BCN Policy Effective Date: 3/17/25
(See policy history boxes for previous effective dates)

Title: Prescription Drugs Covered under the Medical Certificate

Description/Background

This policy applies to all legend prescription drugs administered through the BCN medical certificate, including biologicals, vaccines, sera, prescription parenteral solutions and enteral suspensions. ("Legend drug" means any drug defined by section 503(b) of the federal food, drug and cosmetic act and under which definition its label is required to bear the statement "RX only.") These prescription drugs are covered through the ***basic certificate.*** Coverage of medications administered through the prescription benefit is defined in the individual member's BCN prescription drug rider.

Medical Policy Statement

Certain medications may be covered under the member's base certificate, subject to the specific copayment for that benefit depending on the certificate. The medications covered under the basic certificate include:

- Allergy serum
- Infertility drugs
- Chemotherapy drugs for cancer diagnoses
- Other drugs that are **not** designed to self-administered, including injections or infusions administered in a physician's office (e.g., IV antibiotics, certain intramuscular injections that require close monitoring, etc.)
- Contraceptive drugs (if covered by the individual certificate)

Inclusionary and Exclusionary Guidelines

Base certificate drug coverage:

Inclusions:

1. ***Inpatient and outpatient hospital facility***: Covers drugs and biologicals provided in association with an authorized admission or procedure.
2. ***Physician's office***: Covers drugs that must be administered by the provider, other than by the oral route, for the treatment of illness or injury, including allergy care. In addition, routine pediatric and adult immunizations are covered as preventive services. *(Oral agents may be covered if provided in preparation for treatment.)* Note: Some medications may require pre-service review. Please refer to individual policies or certificates, as applicable.
3. ***Skilled Nursing Facility/Nursing Home:*** Prescription drugs administered by professional staff in a skilled nursing facility are covered under the Skilled Nursing Facility (SNF) benefit. Prescription drugs are not covered under the SNF benefit for basic nursing home care or after the member's SNF benefits are exhausted.
4. ***Home Health Care:*** Intravenous (IV) administered prescription medications, injectable medications, prescription parenteral solutions and enteral suspensions are covered under the Home Health Care benefit to treat the condition for which the patient is receiving home health care.
5. ***Mandated Chemotherapy Coverage:*** In compliance with Michigan law requiring HMO coverage for off-label use of FDA approved antineoplastic drugs, including oral drugs. Chemotherapy drugs are covered under the base certificate subject to the following conditions:
   - The drug must be FDA approved for use in anti-neoplastic therapy, regardless of whether FDA approval is neoplasm specific (e.g., FDA approved for one type of cancer, but used in another).
   - The drug is ordered for a specific type of neoplasm.
   - The drug is used as part of an antineoplastic drug regimen. This would include:
     - Ancillary drugs, which are drugs used to prevent or reduce side effects of the antineoplastic drug. An example of an ancillary drug would be an antiemetic to prevent or reduce the nausea that often follows chemotherapy.
     - Swing drugs, which are drugs that can be used for cancer treatment as well as other disease states. An example of a swing drug is epoetin alfa, which is given for anemia secondary to kidney failure, but can also be given for anemia secondary to chemotherapy drugs.
   - Current medical literature substantiates its efficacy and recognized specialty oncology organizations generally accept the treatment.
   - The physician has obtained informed consent from the patient.

   In administering mandated chemotherapy benefits, the following provision applies: BCN recognizes and is governed by BCBSM policy for specific off-label use of antineoplastic drugs based on the recommendations of the BCBSM Oncology Advisory Panel.
6. ***Infertility Drug Coverage:*** Infertility drugs are covered under the medical certificate. Check individual certificate for applicable copayments. NOTE: There is *no* coverage for infertility medications for selected certificates, including Personal Plus, BCN Advantage or BCN65. Check individual certificate for specific information regarding coverage.

7. ***Termination of Pregnancy Drug Coverage:*** Oral Mifepristone and Misoprostol, although oral drugs, must be administered in a physician's office and are therefore covered under the base certificate. Termination of pregnancy copayments apply.
8. ***Contraceptive Drugs:*** Office administered contraceptive devices and appliances; such as intrauterine devices (IUDs); implantable and injected contraceptives, and diaphragms including measurement, fittings, removal and administration (if the individual certificate covers contraceptive services).
9. ***Allergy Serum:*** Specific copays may apply.

Other copayments or deductibles may apply to the facility charge, office visit or home health service provided in connection with the administration of the drug. Copayments for durable medical equipment or prosthetics and orthotics used to administer drugs in the home may also apply.

Exclusions:

- Post-transplant anti-rejection drugs are not covered under the base certificate. The member must have a prescription drug rider for these medications to be covered.
- Any drug capable of being self-administered which does not fall into any of the categories mentioned above.
- Drugs not approved by the FDA
- Drugs not reviewed or approved by BCN

CPT/HCPCS Level II Codes (*Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

Multiple

Rationale

Specific coverage is based on the individual member certificate and rider language. Chemotherapy drug coverage is based on Michigan law which requires health insurance companies, Blue Cross Blue Shield of Michigan and HMOs to pay for FDA approved drugs used in antineoplastic therapy (chemotherapy) and the reasonable cost to administer them. When the FDA approves a drug to be used in chemotherapy, it does so for the treatment of a specific type of cancer. Since the drug is FDA approved, it can be used for the treatment of other types of cancer. This is known as an "off label" use of a drug. The FDA will not review or approve these multiple uses for drugs. Michigan law provides that an antineoplastic (chemotherapy) drug is covered if it is FDA approved, the current medical literature substantiates its efficacy to treat the type of cancer and the patient is informed that the treatment is an "off label" use.

Government Regulations
National:

People with Medicare may get drugs as part of their inpatient treatment during a covered stay in a hospital or skilled nursing facility (SNF). Generally, part A payments made to the hospital, SNF, or other inpatient setting cover all drugs provided during a covered stay.

Generally, Part B covers drugs that usually are not self-administered. These drugs can be furnished in a physician's office as part of a doctor's service. In a hospital outpatient department, coverage generally is limited to drugs that are given by infusion or injection. If the injection usually is self-administered or isn't given as part of a doctor's service, Part B generally won't cover it, but a person's Medicare drug plan (Part D) **may** cover these drugs under certain circumstances.

In most cases, the yearly Part B deductible applies to these drugs. This means that people with Medicare may have to pay the Part B deductible amount before Medicare pays its share. Part B also covers:

- **Certain shots (vaccinations):**
  - **Flu shots:** In general, one flu shot per flu season. Flu shots typically are given before the start of the flu season, in the late summer, fall, or winter, but some people may get the shot in the spring. This means people with Medicare can sometimes get this preventive shot twice in the same calendar year.
  - **Pneumococcal shots**: A shot to help prevent pneumococcal infections (like certain types of pneumonia). Part B also covers a different second shot one year later. People with Medicare should talk with their doctor or other health care provider to see if they need these shots.
  - **Hepatitis B shots**: A series of 3 shots covered only for people at high or medium risk for Hepatitis B. A person's risk for Hepatitis B increases if the person has hemophilia, End-Stage Renal Disease (ESRD)—permanent kidney failure requiring dialysis or a kidney transplant—or certain conditions that increase the person's risk for infection. Other factors may also increase a person's risk for Hepatitis B. To determine if they're eligible for coverage, people with Medicare should check with their doctor to see if they're at high or medium risk for Hepatitis B.
  - **Other shots**: Some other vaccines when they're directly related to the treatment of an injury or illness (like a tetanus shot after stepping on a nail).

- **Durable Medical Equipment (DME) supply drugs:** Drugs used in connection with approvable durable medical equipment (DME), such as nebulizers and infusion pumps
- **Injectable and infused drugs:** Medicare covers most injectable and infused drugs given by a licensed medical provider if the drug is considered reasonable and necessary for treatment and usually isn't self-administered.
- **Injectable osteoporosis drugs:** Medicare covers an injectable drug for women with osteoporosis who meet the criteria for the Medicare home health benefit and have a bone fracture that a doctor certifies was related to post-menopausal osteoporosis. A doctor must certify that the woman is unable to learn how to or unable to give herself the drug by

injection. The home health nurse or aide won't be covered to provide the injection unless family and/or caregivers are unable or unwilling to give the woman the drug by injection.

- **Some antigens:** Medicare helps pay for antigens if they're prepared by a doctor and given by a properly-instructed person (who could be the patient) under supervision.
- **Erythropoiesis stimulating agents:** Medicare will help pay for erythropoietin by injection if a person with Medicare has ESRD and needs this drug to treat anemia.
- **Blood Clotting factors:** If a person with Medicare has hemophilia, Medicare helps pay for clotting factors they give themselves by injection.
- **Immunosuppressive drugs:** Medicare covers immunosuppressive drug therapy for people who have received an organ or tissue transplant patients if the transplant meets Medicare coverage requirements, the patient has Part A for which Medicare made payments.
  - If a person is entitled to Medicare only because of permanent kidney failure, their Medicare coverage will end 36 months after the month of the transplant. Medicare won't pay for any services or items, including immunosuppressive drugs, for patients who aren't entitled to Medicare.
  - A person with ESRD and Original Medicare may join a Medicare drug plan (Part D). Part D may cover other immunosuppressive drugs not covered by Part B, even if Medicare didn't pay for the transplant.
- **Oral anti-cancer drugs:** Medicare helps pay for some cancer drugs you take by mouth if the same drug is available in injectable form or is a prodrug of the injectable drug. As new oral anti-cancer drugs become available, Part B may cover them.
- **Oral anti-nausea drugs:** Medicare helps pay for oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen. The drugs must be administered immediately before, at, or within 48 hours after chemotherapy drug and must be used as a full therapeutic replacement for an intravenous anti-nausea drug.
- **Parenteral and enteral nutrition (intravenous and tube feeding):** Medicare helps pay for certain nutrients for people who can't absorb nutrition through their intestinal tracts or can't take food by mouth.
- **Intravenous Immune Globulin (IVIG) provided in the home:** Medicare helps pay for IVIG for people with a diagnosis of primary immune deficiency disease. A doctor must decide that it's medically appropriate for the IVIG to be given in the patient's home. Part B covers the IVIG itself, but Part B doesn't pay for other items and services related to the patient getting the IVIG in his or her home.

A Medicare Advantage Plan (Part C) must cover the drugs that are covered under Part A and Part B. A person in a Medicare Advantage Plan will usually get their Medicare prescription drug coverage from their plan. They should contact their plan to see if it offers prescription drug coverage. In most Medicare Advantage Plans, if a person wants drug coverage and their plan offers it, they must get it from their Medicare Advantage Plan. A person can't have prescription drug coverage through both a Medicare Advantage Plan and a Medicare Prescription Drug Plan.

Local:

WPS Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741), effective for services on or after 06/01/18, retired 06/10/19.

The LCD has been promulgated to establish the clinical conditions for which the included drugs are considered to be medically reasonable and necessary and thus, covered by Medicare. The agents discussed in no way constitute a complete list of drugs and biologicals covered by Medicare. This document does not include chemotherapy drugs (See our Chemotherapy LCD). The contractor expects the use of those drugs and biologicals not listed here to be medically necessary and used according to their FDA indications.

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them.

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:

- Be of a form that is not usually self-administered;
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's direct supervision.

The charge, if any, for the drug or biological must be included in the physician's bill and the cost of the drug or biological must represent an expense to the physician.
Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. An LCD reconsideration request with supporting documentation should be submitted via policycomments@wpsic.com to request off label use of a drug.

Limitations:
The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice:

- Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered.
- Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an

accepted or preferred method of administration. For example, the accepted standard of medical practice for the treatment of certain diseases is to initiate therapy with parenteral penicillin and to complete therapy with oral penicillin. Carriers exclude the entire charge for penicillin injections given after the initiation of therapy if oral penicillin is indicated unless there are special medical circumstances that justify additional injections.
- Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered.

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge (i.e., for both the drug and its administration) is not considered medically necessary.

This is not an all-inclusive list and will not be updated to include every newly FDA approved drug.

J0129 Abatacept 10 mg (Orencia™) (Code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)

- Rheumatoid Arthritis
- Felty's Syndrome
- Other rheumatoid arthritis with visceral or systemic involvement
- Juvenile Arthritis
- Adult Psoriatic Arthritis: active PsA in adults

J0129 should only be used when administering intravenously.

J0178 Aflibercept (Eyelea), 1 mg

- Macular Edema Following Central Retinal Vein Occlusion (CRVO)
- Neovascular (Wet) Age-Related Macular Degeneration (AMD)

J0180 Agalsidase Beta 1mg, (Fabrazyme™)
Fabry's disease (Lipidoses)

J0256 Alpha 1 Proteinase Inhibitor-Human, NOT OTHERWISE SPECIFIED,10 mg
Alpha 1-antitrypsin deficiency

J0257 ALPHA 1 PROTEINASE INHIBITOR (HUMAN), (GLASSIA), 10 MG
Alpha 1-antitrypsin deficiency

J0364 Apomorphine hydrochloride 1mg (Apokyn™)
Acute, intermittent treatment of hypomobility associated with advanced Parkinson's disease

J1300 Eculizumab, 10 mg (Soliris™)
Treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis
For the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Effective 09/23/2011-FDA approval date.

J1745 Infliximab 10 mg (Remicade™)

- Behçet Syndrome
- Colitis
- Crohn's disease
- Chronic severe plaque psoriasis
- Psoriatic arthropathy
- Rheumatoid Arthritis
- Felty's Syndrome
- Other rheumatoid arthritis with visceral or systemic involvement
- Juvenile Chronic polyarthritis
- Ankylosing spondylitis
- Sarcoidosis: consideration for treating patients with persistent symptomatic sarcoidosis despite corticosteroid and immunosuppressive treatment will be given.
- Iridocyclitis : Infliximab will be covered for uveitis that is refractory to other immunosuppressive agents. Failure of previously used agents must be documented in the medical record

J1931 Laronidase 0.1mg (Aldurazyme™)
Indicated for patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms.

J2001 Lidocaine HCL 10 mg

- Paroxysmal Ventricular Tachycardia
- Ventricular fibrillation
- Ventricular flutter
- Cardiac Arrest
- Other-Ventricular premature beats
- Cardiac Dysrhythmia

J2323 Natalizumab 1 mg, (Tysabri™)

- Multiple Sclerosis
- Crohn's disease will be covered for moderate to severely active Crohn's disease (CD) with evidence of inflammation for patients who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF.

J2357 Omalizumab 5mg, (Xolair™)
Extrinsic Asthma, unspecified **J2503 Pegaptanib sodium .3mg, (Macugen™)**

- Diabetic macular edema
- Central vein occlusion
- "Wet" macular degeneration

J2562 Plerixafor, 1mg, (Mozobil™)
Indicated to be used in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent

autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma

J2778 Ranibizumab .1mg, (Lucentis™)

- Proliferative diabetic retinopathy
- "Wet" macular degeneration
- Macular edema following Retinal vein occlusion (RVO):code macular edema **and** Central retinal vein occlusion (CRVO) **or** Venous tributary (branch) occlusion (BRVO).
- Retinal neovascularization-choroidal
- Diabetic macular edema

J2796 Romiplostim 10 mcg (Nplate™)

For the treatment of thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.

J3396 Verteporfin, 0.1 mg (Visudyne™)

See National Coverage Determinations Manual 100-03 Section 80.3.

Verteporfin is covered with a diagnosis of neovascular age-related macular degeneration with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50 percent of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram. Additional FDA approved indications include pathologic myopia and presumed ocular histoplasmosis

J3590 Bevacizumab (Avastin™) 1-3 mg- (Use for administration in the office setting)
C9257 Bevaciumab 0.25 mg (For hospital outpatient and ASC settings)

- Infection by histoplasma capsulatum-retinitis
- Infection by histoplasma duboisii-retinitis
- Ocular histoplasmosis
- Proliferative diabetic retinopathy
- Diabetic macular edema
- Central retinal vein occlusion
- Venous tributary (branch) occlusion
- Rubeosis iridis
- "Wet" macular degeneration
- Cystoid macular degeneration
- Glaucoma associated vascular disorders
- Retinal neovascularization-choroidal
- Macular edema

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. Wisconsin Physician's Service website. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Information available at http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32013&ContrId=267 Last accessed February 2024. Retired.
2. BCN certificate language.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 2025, the date the research was completed.

BCN Medical Policy History

Date	Rationale
10/1/97	BCN medical policy created
12/14/00	Routine maintenance
01/16/01	Routine maintenance
8/16/05	Policy updated, reformatted
09/24/06	Routine maintenance
5/21/08	Routine maintenance
2/17/10	Routine maintenance
3/20/13	Policy title and focus changed from “Prescription Drugs” to “Prescription Drugs Covered under the Medical Certificate.”
4/16/14	No changes to current policy.
4/15/15	Routine maintenance
3/16/16	Routine maintenance, no change in policy status
5/17/17	Routine maintenance
5/16/18	Routine policy maintenance. Removed all ICD-9 codes from policy.
5/15/19	Routine policy maintenance. Removed Medicaid section, updated LCD.
3/12/20	Routine policy maintenance. Updated status of LCD.
3/11/21	Routine policy maintenance. No change in policy status.
3/10/22	Routine policy maintenance. No change in policy status.
3/9/23	Routine policy maintenance, no change in policy status. Removed “and preauthorization decisions” from Inclusion/Exclusion section.
3/14/24	Added two bullets under exclusions per certificate language. Routine policy maintenance, no change in status. Vendor managed: N/A (ds)
3/17/25	Routine policy maintenance, no change in status. Vendor managed: N/A (ds)

Next Review: 1st Qtr. 2026

MEDICAL POLICY TITLE: PRESCRIPTION DRUGS COVERED UNDER THE MEDICAL CERTIFICATE
BCN BENEFIT ADMINISTRATION

I. Coverage Determination

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.