| Priority Health | BILLING POLICY<br>No. 084 |
|---|---|

# DRUGS ADMINISTERED BY PROVIDERS FOR FDA-APPROVED OR MEDICALLY ACCEPTED OFF-LABEL USES

| Date of origin: Apr. 15, 2025 | Review dates: 8/2025 |
|---|---|

## APPLIES TO

- Commercial
- Medicare follows CMS unless otherwise specified
- Medicaid follows MDHHS unless otherwise specified

## DEFINITION

This policy outlines the criteria and guidelines for reimbursement of FDA-approved medications for use of labeled and off-labeled indications. The purpose is to ensure the appropriate indications are adhered to for appropriate use, safety and effective use of medications while managing health care costs. This policy also details the different methods for administering and billing medications.

An off-label or unlabeled use of a medication refers to its application for a purpose that hasn't received approval from the FDA, meaning it isn't included in the official labeling or prescribing information for that drug. An indication encompasses any diagnosis, illness, injury, syndrome, condition or clinical parameter for which the drug may be prescribed. This definition includes, but isn't limited to aspects such as dosage, method of administration, duration of treatment, frequency of dosing and the demographic group that will receive the medication.

Use of a drug for indications not included in its approved labeling may be eligible for coverage if it's deemed a medically accepted indication. This determination will take into account major drug compendia, reputable medical literature and recognized standards of medical practice. Consideration for emerging evidence and clinical guidelines is assessed. Off-label use may require prior authorization unless otherwise stated in our Provider Manual. Documentation to support medical necessity may be requested, including clinical rationale and supporting evidence. Refer to our prior auth requirements for further detail.

## POLICY SPECIFIC INFORMATION

### Clinical evidence

Off-label use must be supported by clinical evidence, such as peer-reviewed medical literature, clinical guidelines or consensus statements from recognized medical organizations. This evidence should demonstrate that the off-label use is safe and effective for the proposed indication.

Off-label use must be prescribed by allopathic or osteopathic physicians who have the necessary qualifications and expertise to determine the appropriateness of the off-label use. Priority Health follows state and CMS guidance for accepted literature for off-label use.

Search our online formulary tools to understand drug coverage information by plan, including formulary status for a specific drug and if there are utilization management rules like prior authorization requirements, step therapy requirements, age limits and/or quantity limits.

### Place of service

Priority Health requires that patients receiving selected infusions or injections to have the infusion or injection at an approved site of care. Medications with site of service requirements can be found in Priority Health's Medical Benefit Drug List (MBDL). Exceptions may be considered if criteria is met. Learn more in our Provider Manual.

## Billing guidelines

Priority Health will adhere to FDA approved indications unless otherwise defined within the provider manual. Applies to brand name and generic version of drug or biological.

Medications meeting FDA-approved indications are reimbursed when the following exist:

- Administered on or after the FDA's date of approval
- Medical necessity is supported in the medical record for member
- Applicable coverage requirements are met

Dosage and frequency of dosage for drug administered outside of the FDA approved indications will be denied. Age-related criteria defined within the drug label should also be adhered to.

The method of administration for this drug should be aligned to label requirements and align to the duration of treatment.

Note: Specific off-label use may be defined by other policies within our Provider Manual and supersede these guidelines.

Provider should validate that drugs or biologicals align to FDA approved or medically accepted off-label use in relation to the following:

- Coverage
- Diagnosis criteria
- Diagnosis sequencing
- Frequency to dosage indications
- Date of service units
- Units over time
- Modifiers usage
- Any other criteria defined for these drugs.

**This may not be all inclusive listing – refer to the FDA requirements for further detail.*

## Documentation requirements

Complete and thorough documentation to substantiate the procedure performed is the responsibility of the provider. In addition, the provider should consult any specific documentation requirements that are necessary of any applicable defined guidelines.

The medical record must contain documentation to fully support the medical necessity for the services provided. This documentation may include relevant medical history, physical examination and results of pertinent diagnostic tests or procedures.

In addition, the following documentation is necessary:

- The name of the drug or biological administered
- The route of administration
- The dosage (e.g., mgs, mcgs, cc's or IU's)
- The duration of the administration (some CPT codes may be time based)
- Include the correct range: If a drug is given over several days, include the corresponding date range of when the doses were administered, so as not to exceed the maximum units per dose or day.
- Observe minimum dosing intervals: There are some drugs that have minimum dosing interval limitations, which may be impacted by these edits (e.g., Prolia given every 6 months or Reclast given once yearly).
- Medical records may be requested for review of dosage and/or dosing intervals reported on claims.

- Units reported must correspond with the smallest dose (vial) available from drug manufacturer or pharmacy for purchase. This allows for minimal waste or discarded drug or biological.

## Administration codes

Below is a listing of commonly used administration codes. This list isn't all inclusive. Consult the CPT manual to report the most appropriate code which is supported by documentation.

Review all applicable code lay descriptions as start and stop times documentation may be required.

Administration services related to non-covered drugs will be denied.

- **96372**: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
- **96374**: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
- **96375**: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug (List separately in addition to code for primary procedure)
- **96365**: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
- **96366**: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (List separately in addition to code for primary procedure)
- **96367**: Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion of a new drug/substance, up to 1 hour (List separately in addition to code for primary procedure)
- **96413**: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- **96415**: Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)

## Drugs and Biologicals

Examples of drugs aligned to policy criteria are detailed below. This is not an all-inclusive list – refer to the drugs or biologicals outlined by the FDA.

Vutrisiran (J0225)
Paliperidone Palmitate (J2426))
Lutetium Lu 177 vipivotide tetraxetan (A9607)
Esketamine, Nasal Spray (G2082, G2083, S0013)
Immune Globulins, SQ (90284, J1559, J1562)
Durvalumab (J9173)
Lanreotide (J1930, J1932)
Remicade; Inflectra; Ixifi, Renflexis, Avsola (J1745, Q5103, Q5104, Q5109, or Q5121)
Rituximab (J9312, Q5115, Q5119, Q5123)
Immune Globulins, IV (90283, J1459, J1556, J1557, J1561, J1566, J1568, J1569, J1572, or J1599)
Cemiplimab (J9119)
Paliperidone palmitate (Invega Hafyera, Invega Trinza) (J2427)
Faricimab (J2777)
Daratumumab (J9145)
Tildrakizumab (J3245)
Belatacept (J0485)
Burosumab (J0584)
Golimumab (J1602)
Cabotegravir and Rilpivirine (J0741)
Carfilzomib (J9047)
Buprenorphine Extended-Release (Q9991, Q9992)

Ocrelizumab (J2350)
Ferric Derisomaltose (J1437)
Vedolizumab (J3380)
Botulinum Toxin A (J0585)
Fluocinolone Acetonide Intravitreal (Yutiq) J7314
Risankizumab (J2327)
Pegfilgrastim (J2506, Q5108, Q5111, Q5120, Q5122, Q5127, Q5130)
Vedolizumab (J3380)
Ipilimumab (J9228)
Nirsevimab (90380, 90381)
Naltrexone depot (J2315)
Pembrolizumab (J9271)
Botulinum Toxin A (J0586)
Ocrelizumab (J2350)
Infliximab J1745, Q5103, Q5104, Q5109, Q5121
Botulinum Toxin B (J0587)
Sodium Hyaluronan or Derivative (J7318, J7320-J7329, J7331, J7332)
Botulinum Toxin A J0585
Botulinum Toxin A (J0588)
Aprepitant (J0185)
Buprenorphine (Brixadi) (J0577, J0578)
Denosumab (J0897, Q5136)
Abatacept (J0129)
Pembrolizumab (J9271)
Aflibercept HD (J0177)
Aripiprazole Lauroxil (J1943, J1944)
Remdesivir (J0248)
Infliximab (J1745, Q5103, Q5104, Q5109, Q5121)
Botulinum Toxin A (J0585)
Ipilimumab (J9228)
BCG (Intravesical) (J9030)
Buprenorphine Extended-Release (Q9991, Q9992)
Ipilimumab J9228
Naltrexone depot (J2315)
Buprenorphine Extended-Release (Q9991, Q9992)
Nirsevimab (90380, 90381)

## Modifiers

Priority Health follows standard billing and coding guidelines which include CMS NCCI. Modifiers should be applied when applicable based on this guidance and only when supported by documentation.

Incorrect application of modifiers will result in denials. The modifier list below may not be an all-inclusive list. Learn more about modifier use in our Provider Manual.

- **JW**: Drug amount discarded/not administered to any patient
- **JZ**: Zero drug amount discarded/not administered to any patient
- **59**: Distinct Procedural Service (applicable to the administration, when appropriate and supported by documentation)

When using modifier JW to indicate that part of a drug or biological product from a single-use vial has been discarded, the medical record must clearly show both the amount given to the patient and the amount that was wasted or discarded.

The JZ Modifier must be included on all claims for drugs that are billed separately under Medicare Part B when there is no waste from single-dose containers or single-use packages.

## Definitions

- **Off-label use** – the use of a drug for clinical indications other than those stated in the labeling approved by the United States Food and Drug Administration.
- **Indication** – diagnosis, illness, injury, syndrome, condition for which a drug may be given.
- **Administration** – the route in which the drug may be given
- **Physician Administered drug** – a medication administered in a physician's office or outpatient clinic setting by a healthcare provider.
- **FDA (Food and Drug Administration)** – the (FDA) safeguards public health by ensuring the safety, effectiveness, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and radiation-emitting products.
- **Benefits Exclusions** – specific drug, class of drugs, or intended use of a drug which is excluded from a member's benefit per their Certificate of Coverage, a rider, or other plan documents (MDHHS contract, Medicaid Provider Manual, etc.)
- **Experimental/Investigational/Unproven Care** – requests for drugs which have been determined to be Experimental/Investigational/Unproven Care and as such are excluded. This may also be supported through a member's Certificate of Coverage.

## Resources

- LCD - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394)
- Article - Billing and Coding: Drugs and Biologicals (A52855)
- Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers
- eCFR :: Title 21 of the CFR -- Food and Drugs
- Food and Drug Administration (FDA)
- MCL - Section 500.3406q - Michigan Legislature

## Related policies

- 91414 – Infusion Services and Equipment

# DISCLAIMER

Priority Health's billing policies outline our guidelines to assist providers in accurate claim submissions and define reimbursement or coding requirements if the service is covered by a Priority Health member's benefit plan. The determination of visits, procedures, DME, supplies and other services or items for coverage under a member's benefit plan or authorization isn't being determined for reimbursement. Authorization requirements and medical necessity requirements appropriate to procedure, diagnosis and frequency are still required. We use Current Procedural Terminology (CPT), Centers for Medicare and Medicaid Services (CMS), Michigan Department of Health and Human Services (MDHHS) and other defined medical coding guidelines for coding accuracy.

An authorization isn't a guarantee of payment when proper billing and coding requirements or adherence to our policies aren't followed. Proper billing and submission guidelines must be followed. We require industry standard, compliant codes defined by CPT, HCPCS and revenue codes for all claim submissions. CPT, HCPCPS, revenue codes, etc., can be reported only when the service has been performed and fully documented in the medical record to the highest level of specificity. Failure to document for services rendered or items supplied will result in a denial. To validate billing and coding accuracy, payment integrity pre- or post-claim reviews may be performed to prevent fraud, waste and abuse. Unless otherwise detailed in the policy, our billing policies apply to both participating and non-participating providers and facilities.

If guidelines detailed in government program regulations, defined in policies and contractual requirements aren't followed, Priority Health may:

- Reject or deny the claim
- Recover or recoup claim payment

An authorization on file for an item or services doesn't supersede coding, billing or reimbursement requirements.

These policies may be superseded by mandates defined in provider contracts or state, federal or CMS contracts or requirements. We make every effort to update our policies in a timely manner to align to these requirements or contracts. If there's a delay in implementation of a policy or requirement defined by state or federal law, as well as contract language, we reserve the right to recoup and/or recover claim payments to the effective dates per our policy. We reserve the right to update policies when necessary. Our most current policy will be made available in our Provider Manual.

---

## CHANGE / REVIEW HISTORY

| Date | Revisions made |
|---|---|
| Aug. 14, 2025 | Added "Drugs and biologicals" section |