

Outpatient Prescription Drugs

Benefit Coverage

Drugs eligible for coverage under a Blue Shield member's outpatient prescription drug benefit are those that meet all of the requirements specified in this guideline, are prescribed by participating licensed prescriber and, except as noted below, are obtained from a Participating Pharmacy.

The list of covered drugs maintained by the Blue Shield of California Pharmacy and Therapeutics (P&T) Committee, is designed to assist physicians in prescribing medically-appropriate, cost-effective drug therapy. The formulary contains medications approved by the Food & Drug Administration (FDA) which have been reviewed for safety, efficacy, bio-equivalency, and cost. The P&T Committee is the governing committee responsible for oversight and approval of policies and procedures pertaining to formulary management, drug utilization, pharmacy-related quality improvement, educational programs and utilization management programs, and other drug issues related to patient care. The committee determines clinical drug preference for formulary inclusion, medication coverage policies and clinical coverage requirements based on the medical evidence for comparative safety, efficacy and cost when safety & efficacy are similar. The voting members of the P&T Committee are practicing physicians and pharmacists in the Blue Shield network who are not employees of Blue Shield. The P&T Committee reviews drugs on a quarterly basis.

Drugs and associated supplies eligible for coverage are defined as:

- Drugs approved by the Food and Drug Administration (FDA), requiring a prescription either by federal or California law, and prescribed for treatment of a medically necessary condition according to the FDA label, or for off-label uses and doses when:
 - supported by clinical compendia defined in federal and California law, or
 - supported in two articles from major peer reviewed medical journals with data demonstrating use or uses as safe and effective unless there is contradictory evidence presented in a major peer reviewed medical journal.
- Contraceptive drugs and devices, including female OTC contraceptives.
- Over-the-counter (OTC) drugs with a United States Preventive Services Task Force (USPSTF) rating of A or B.
- Insulin and disposable hypodermic insulin syringes and needles for administration of insulin.

Outpatient Prescription Drugs

Benefit Coverage *(cont'd.)*

- Pen delivery systems for the administration of insulin as medically necessary.
- Diabetic testing supplies, including lancets, lancet puncture devices, blood and urine testing strips, and test tablets. For blood glucose test strips obtained at the pharmacy, coverage is limited to specific manufacturer brands.
- Inhalers and inhaler spacers for the management and treatment of asthma.

Note: Coverage of listed supplies requires a prescription.

When the Blue Shield P&T Committee removes a drug from formulary (i.e. non-formulary), and ongoing use of that drug is required to treat a chronic condition or to maintain health, the drug will continue to be covered for the member as long the member remains eligible and the medication continues to be prescribed for that member.

Maintenance Medication: When a member's medication dosage is stabilized and taken on an ongoing, regular basis to maintain health, the member may obtain the prescription through the Mail Service Prescription Drug Program for up to a 90-day supply. In order for a prescription to be filled by a mail service pharmacy, or to be transferred from a retail pharmacy to a mail service pharmacy, a new prescription with a quantity sufficient to cover up to a 90-day supply is required.

Specialty Drugs: Specialty drugs are drugs that may be manufactured using special processes, require special handling, coordination of care, close monitoring, or extensive patient training for safe self-administration that generally cannot be met by a retail pharmacy, and are available at a Network Specialty Pharmacy. Specialty drugs may also be drugs restricted by the FDA or drug manufacturer to prescribing by certain physicians or dispensing at certain pharmacies. A Network Specialty Pharmacy provides Specialty Drugs by mail or, upon a member's request, at an associated retail pharmacy for pickup.

- The list of specialty drugs and information about Network Specialty Pharmacies may be accessed at blueshieldca.com.
- New prescriptions for specialty drugs should be sent to a Network Specialty Pharmacy.

Outpatient Prescription Drugs

Prior Authorizations and Exceptions

Prior Authorization: Most medications are covered without prior authorization. However, some medications require the patient's prescription and medical history to establish medical necessity and to evaluate use of preferred, formulary alternatives prior to coverage.

Exceptions: Medications not covered under a member's benefit or that are prescribed outside of coverage rules require an exception for coverage based on medical necessity. Types of exceptions include:

- Formulary exceptions. Coverage of a non-formulary (non-listed) drug when formulary alternatives are not appropriate for the individual patient.
- Waiver of coverage restrictions or limits, such as prescription quantity limits or step therapy protocols for prior use of preferred drugs.
- Drugs obtained from a non-participating pharmacy due to a covered emergency

To request prior authorization or an exception to cover a medication for a Blue Shield member, call Blue Shield's Pharmacy Services prior authorization center at (800) 535-9481, or complete and fax the California standard Prescription Drug Prior Authorization Request Form (available at blueshieldca.com/provider) to (888) 697-8122. Evidence of medical necessity may include submission of studies published in major peer reviewed medical journals and/or a patient's medical records.

Copayment

The member is responsible for any deductibles and the plan copayment or coinsurance as described in the member's *Evidence of Coverage* and *Summary of Benefits*.

If a brand name drug is dispensed when a generic is available upon request of the member or prescriber, the member may be responsible for paying the difference between the cost of the brand name drug and its generic equivalent, in addition to the generic copayment. Exceptions may be granted to cover the brand name drug at a plan copayment if medically necessary and use of the generic equivalent is not clinically appropriate for the individual patient.

Blue Shield members are responsible for paying 100% of the cost of the drug(s) if not a covered benefit unless a prior authorization or exception is obtained.

Outpatient Prescription Drugs

Benefit Exclusions

No benefits are provided for:

- Prescription drugs dispensed by non-participating pharmacies, except for emergency coverage.
- Non-formulary drugs for members with a benefit only for formulary drugs, unless coverage is granted subsequent to an exception request.
- Any drug covered under the member's medical benefit, including:
 - drugs provided or administered by a healthcare provider in a hospital, physician's office, Skilled Nursing Facility, Outpatient Facility, or infusion center
 - take-home drugs received from a hospital, skilled nursing facility, or similar facility
 - drugs provided as part of the home health benefit or by home infusion service
 - blood or blood products
- Drugs that are only available without a prescription (over-the counter) and prescription drugs that have a non-prescription version that is an identical chemical equivalent (i.e., same active ingredient and dosage).
- Drugs that are considered to be experimental or investigational.
- Medical devices or supplies unless specifically listed as covered.
- Topically applied prescription preparations that are approved by the FDA as medical devices.
- Drugs when prescribed for cosmetic purposes, including but not limited to drugs used to retard or reverse the effects of skin aging or to treat hair loss.
- Dietary or nutritional products (see the *HMO Benefit Guidelines* on PKU and Home Health Services for possible coverage under the medical benefit).
- All drugs for the treatment of infertility.
- Appetite suppressants or drugs for body weight reduction except when medically necessary for the treatment of morbid obesity. In such cases the drug will be subject to prior authorization from Blue Shield.

Outpatient Prescription Drugs

Benefit Exclusions *(cont'd.)*

- Contraceptive drugs or devices covered under the medical benefit (IUDs, injections or implants).
- Compounded medications that: (1) do not include at least one drug ingredient, (2) do not have an FDA-approved, commercially available alternative(s) that is medically appropriate for the patient for self-administration, and (3) are not used to treat a medically accepted indication as described in the FDA label or supported in clinical compendia defined in federal and state law, or supported in the medical literature.
- Replacement of lost, stolen or destroyed prescription drugs.
- Pharmaceuticals that are reasonable and necessary for the palliation and management of terminal illness and related conditions if they are provided to a member enrolled in a hospice program through a participating hospice agency.
- Drugs prescribed for treatment of dental conditions. (This exclusion shall not apply to antibiotics prescribed to treat infection or to medications prescribed to treat pain.)
- Drugs obtained from a Pharmacy not licensed by the State Board of Pharmacy or included on a government exclusion list, except for a covered emergency.
- Immunizations and vaccinations by any mode of administration (oral, injection or otherwise) solely for the purpose of travel.
- Drugs packaged in convenience kits that include non-prescription convenience items, unless the drug is not available without the non-prescription components. This exclusion shall not apply to items used for the administration of diabetes or asthma drugs.

Benefit Limitations

- Repackaged prescription drugs (drugs that are repackaged by an entity other than the original manufacturer).
- Outpatient Prescription Drugs obtained at a Participating Pharmacy are limited to a 30-day supply.

Outpatient Prescription Drugs

Benefit Limitations *(cont'd.)*

- Outpatient Prescription Drugs obtained at mail service pharmacy according to the Mail Service Prescription Drugs Program may fill up to a 90-day supply of maintenance medication.
- Dispensing limits as described in the drug formulary.

Examples of Covered Services

- Blue Shield of California Formulary Drugs. (Select drugs and drug dosages require prior authorization or an exception by Blue Shield.)

Examples of Non-Covered Services

- Hypodermic needles/syringes used with drugs other than insulin
- Support garments and similar items
- Bevacizumab (Avastin) infused in the provider office or infusion center
- Retin A for members over 40 years of age
- Antifungal drugs prescribed for cosmetic purposes

References

Outpatient Prescription Drug Benefit Supplement to Evidence of Coverage

HMO Benefit Guidelines for:

Drugs-Basic Plan

Infertility-Basic

Hospice Care

Infertility-CalPERS

Infertility-Additional Benefits

Medical Benefit Drugs

Blue Shield Pharmacy Customer Service and Drug Prior Authorization Units

Blue Shield Drug Formularies – Plus, Standard and Medicare