Medications and Off-Label Drugs

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Instructions for Use

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Federal/State Mandated Regulations

CA Health & Safety Code §1367.21
Applies to Policies Issued and/or Renewed On or After January 1, 2010; Prescription Drug Coverage for Other Than Approved Uses

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1367.21

(a) No health care service plan contract which covers prescription drug benefits shall be issued, amended, delivered, or renewed in this state if the plan limits or excludes coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that all of the following conditions have been met:
  (1) The drug is approved by the FDA.
  (2) (A) The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition; or
    (B) The drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the plan formulary. If the drug is not on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.
  (3) The drug has been recognized for treatment of that condition by any of the following:
    (A) The American Hospital Formulary Service's Drug Information
    (B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:
      (i) The Elsevier Gold Standard's Clinical Pharmacology
      (ii) The National Comprehensive Cancer Network Drug and Biologics Compendium
      (iii) The Thomson Micromedex DrugDex

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(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of subdivision (a), if requested by the plan.

(c) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

(d) For purposes of this section, "life-threatening" means either or both of the following:
(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted
(2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival

(e) For purposes of this section, "chronic and seriously debilitating" means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

(f) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

(g) Nothing in this section shall be construed to prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

(h) If a plan denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under Section 1370.4.

(i) Health care service plan contracts for the delivery of Medi-Cal services under the Waxman-Duffy Prepaid Health Plan Act (Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code) are exempt from the requirements of this section.

CA Health & Safety Code §1367.24 – Coverage for Nonformulary Drugs

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1367.24.

(a) Every health care service plan that provides prescription drug benefits shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. On or before July 1, 1999, every health care service plan that provides prescription drug benefits shall file with the department a description of its process, including timelines, for responding to authorization requests for nonformulary drugs. Any changes to this process shall be filed with the department pursuant to Section 1352. Each plan shall provide a written description of its most current process, including timelines, to its prescribing providers. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4040 of the Business and Professions Code, to treat a medical condition of an enrollee.

(b) Any plan that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval in a notice provided to the enrollee. The notice shall indicate that the enrollee may file a grievance with the plan if the enrollee objects to the disapproval, including any alternative drug or treatment offered by the plan. The notice shall comply with subdivision (b) of Section 1368.02. Any health plan that is required to maintain an external exception request review process pursuant to subdivision (k) shall indicate in the notice required under this subdivision that the enrollee may file a grievance seeking an external exception request review.

(c) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically necessary nonformulary drugs shall not apply to a nonformulary drug that has been prescribed for an enrollee in conformance with the provisions of Section 1367.22.

(d) The process described in subdivision (a) by which enrollees may obtain medically necessary nonformulary drugs, including specified timelines for responding to prescribing provider authorization requests, shall be described in evidence of coverage and disclosure forms, as required by subdivision (a) of Section 1363, issued on or after July 1, 1999.

(e) Every health care service plan that provides prescription drug benefits shall maintain, as part of its books and records under Section 1381, all of the following information, which shall be made available to the director upon request:
(1) The complete drug formulary or formularies of the plan, if the plan maintains a formulary, including a list of the prescription drugs on the formulary of the plan by major therapeutic category with an indication of whether any drugs are preferred over other drugs.
(2) Records developed by the pharmacy and therapeutic committee of the plan, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

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(3) Any plan arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the plan to encourage formulary compliance or otherwise manage prescription drug benefits.

(f) If a plan provides prescription drug benefits, the department shall, as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, review the performance of the plan in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the plan as part of its report issued pursuant to Section 1380.

(g) The director shall not publicly disclose any information reviewed pursuant to this section that is determined by the director to be confidential pursuant to state law.

(h) For purposes of this section, "authorization" means approval by the health care service plan to provide payment for the prescription drug.

(i) Nonformulary prescription drugs shall include any drug for which an enrollee's copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation or in cases in which the drug has been excluded in the plan contract pursuant to Section 1342.7.

(j) Nothing in this section shall be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367, which includes among its requirements that a health care service plan furnish services in a manner providing continuity of care and demonstrate that medical decisions are rendered by qualified medical providers unhindered by fiscal and administrative management.

(k) For any individual, small group, or large health plan contracts, a health care service plan's process described in subdivision (a) shall comply with the request for exception and external exception request review processes described in subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall not apply to Medi-Cal managed care health care service plan contracts as described in subdivision (l).

(l) "Medi-Cal managed care health care service plan contract" means any entity that enters into a contract with the State Department of Health Care Services pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

(m) Nothing in this section shall be construed to affect an enrollee's or subscriber's eligibility to submit a grievance to the department for review under Section 1368 or to apply to the department for an independent medical review under Section 1370.4, or Article 5.55 (commencing with Section 1374.30) of this chapter.

CA. Health & Safety Code §1367.06

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1367.06.

(a) A health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered, or renewed on or after January 1, 2005, that covers outpatient prescription drug benefits shall include coverage for inhaler spacers when medically necessary for the management and treatment of pediatric asthma.

(b) If a subscriber has coverage for outpatient prescription drugs, a health care service plan contract, except a specialized health care service plan contract, that is issued, amended, delivered or renewed on or after January 1, 2005 shall include coverage for the following equipment and supplies when medically necessary for the management and treatment of pediatric asthma:
(1) Nebulizers, including face masks and tubing
(2) Peak flow meters

(c) The quantity of the equipment and supplies required to be covered pursuant to subdivisions (a) and (b) may be limited by the health care service plan if the limitations do not inhibit appropriate compliance with treatment as prescribed by the enrollee's physician and surgeon. A health care service plan shall provide for an expeditious process for approving additional or replacement inhaler spacers, nebulizers, and peak flow meters when medically necessary for an enrollee to maintain compliance with his or her treatment regimen. The process required by Section 1367.24 may be used to satisfy the requirements of this section for an inhaler spacer.

(d) Education for pediatric asthma, including education to enable an enrollee to properly use the device identified in subdivisions (a) and (b), shall be consistent with current professional medical practice.

(e) The coverage required by this section shall be provided under the same general terms and conditions, including copayments and deductibles, applicable to all other benefits provided by the plan.

(f) A health care service plan shall disclose the benefits under this section in its evidence of coverage and disclosure forms.

(g) A health care service plan may not reduce or eliminate coverage as a result of the requirements of this section.

(h) Nothing in this section shall be construed to deny or restrict in any way the department's authority to ensure plan compliance with this chapter, if a plan provides coverage for prescription drugs.

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CA. Health & Safety Code §1342.71

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1342.71

(a) The Legislature hereby finds and declares all of the following:
  (1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.
  (2) The Legislature intends to build on the existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.
  (3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A non-grandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the contract that constitute essential health benefits, as defined in Section 1367.005.

(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.

(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.
  (2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(e) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(f) (1) This section shall not be construed to require a health care service plan to impose cost sharing.
  (2) This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.
  (3) A plan's prescription drug benefit shall provide that if the pharmacy's retail price for a prescription drug is less than the applicable copayment or coinsurance amount, the enrollee shall not be required to pay more than the retail price. The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription medication by paying the cost-sharing amount.

(g) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

(h) This section does not apply to a health care service plan contract with the State Department of Health Care Services.

(Amended (as amended by Stats. 2016, Ch. 86, Sec. 175) by Stats. 2018, Ch. 787, Sec. 1. (SB 1021) Effective January 1, 2019.)

CA Health & Safety Code §1342.72

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1342.72.

(a) For combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, a health care service plan shall not have utilization management policies or procedures, including a standard of care, which rely on a multitablet drug regimen instead of a single-tablet drug regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and equally or more likely to result in adherence to a drug regimen.

(b) This section does not apply to a health care service plan contract with the State Department of Health Care Services.

(c) This section shall remain in effect only until January 1, 2023, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2023, deletes or extends that date.

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CA Health & Safety Code §1342.73

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1342.73

(a) (1) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).

(3) For a health care service plan contract that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an enrollee's deductible has been satisfied for the year.

(4) For a non-grandfathered individual or small group health care service plan contract, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.

(b) (1) If a health care service plan contract for a non-grandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the Food and Drug Administration of the United States Department of Health and Human Services or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars ($600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the health care service plan shall take into account the other provisions of this section and this chapter.

(3) A health care service plan contract may maintain a drug formulary with fewer than four tiers. A health care service plan contract shall not maintain a drug formulary with more than four tiers.

(4) This section shall not be construed to limit a health care service plan from placing any drug in a lower tier.

(c) This section does not apply to a health care service plan contract with the State Department of Health Care Services.

(d) This section shall remain in effect only until January 1, 2024, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2024, deletes or extends that date.

CA Health and Safety Code §1367.41

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1367.41

(a) Commencing January 1, 2017, a health care service plan shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the plan delegates responsibility for the formulary to any entity, the obligation of the plan to comply with this chapter shall not be waived.

(b) The pharmacy and therapeutics committee board membership shall conform with both of the following:

(1) Represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(2) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.

(c) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.

(d) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.

(e) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding the development of, or revisions to, the formulary drug list.

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(f) The pharmacy and therapeutics committee shall do all of the following:
  (1) Develop and document procedures to ensure appropriate drug review and inclusion.
  (2) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information.
  (3) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.
  (4) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.
  (5) Evaluate and analyze treatment protocols and procedures related to the plan's formulary at least annually.
  (6) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.
  (7) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.
  (8) Ensure that the plan's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and do not discourage enrollment by any group of enrollees.
  (9) Ensure that the plan's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.

(g) This section shall be interpreted consistent with federal guidance issued under paragraph (3) of subdivision (a) of Section 156.122 of Title 45 of the Code of Federal Regulations. This section shall apply to the individual, small group, and large group markets.

CA Health and Safety Code §1367.42

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1367.42.&lawCode=HSC

(a) For plan years commencing on or after January 1, 2017, a plan that provides essential health benefits shall allow an enrollee to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.

(b) A non-grandfathered individual or small group health plan contract may charge an enrollee a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the plan's annual limitation on cost sharing consistent with Section 1367.006.

CA Health and Safety Code §1367.47

https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=1367.47.&lawCode=HSC

(a) The maximum amount a health care service plan may require an enrollee to pay at the point of sale for a covered prescription drug is the lesser of the following:
  (1) The applicable cost-sharing amount for the prescription drug.
  (2) The retail price.

(b) A health care service plan shall not require a pharmacist or pharmacy to charge or collect from an enrollee a cost-sharing amount that exceeds the total retail price for the prescription drug.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(Added by Stats. 2018, Ch. 770, Sec. 2. (AB 2863) Effective January 1, 2019.)

CA Health and Safety Code §1367.205.

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1367.205.

(a) In addition to the list required to be provided under Section 1367.20, a health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall do all of the following:
  (1) Post the formulary or formularies for each product offered by the plan on the plan's Internet Web site in a manner that is accessible and searchable by potential enrollees, enrollees, providers, the general public, the department, and federal agencies as required by federal law or regulations.
  (2) Update the formularies posted pursuant to paragraph (1) with any change to those formularies on a monthly basis.
  (3) No later than six months after the date that a standard formulary template is developed under subdivision (b), use that template to display the formulary or formularies for each product offered by the plan.

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(b) (1) By January 1, 2017, the department and the Department of Insurance shall jointly, and with input from interested parties from at least one public meeting, develop a standard formulary template for purposes of paragraph (3) of subdivision (a). In developing the template, the department and Department of Insurance shall take into consideration existing requirements for reporting of formulary information established by the federal Centers for Medicare and Medicaid Services. To the extent feasible, in developing the template, the department and the Department of Insurance shall evaluate a way to include on the template, in addition to the information required to be included under paragraph (2), cost-sharing information for drugs subject to coinsurance.

(1) The standard formulary template shall include the notification described in subdivision (c) of Section 1363.01, and as applied to a particular formulary for a product offered by a plan, shall do all of the following:

(A) Include information on cost-sharing tiers and utilization controls, including prior authorization or step therapy requirements, for each drug covered by the product.

(B) Indicate any drugs on the formulary that are preferred over other drugs on the formulary.

(C) Include information to educate enrollees about the differences between drugs administered or provided under a health care service plan's medical benefit and drugs prescribed under a health care service plan's prescription drug benefit and about how to obtain coverage information regarding drugs that are not covered under the plan's prescription drug benefit.

(D) Include information to educate enrollees that health care service plans that provide prescription drug benefits are required to have a method for enrollees to obtain prescription drugs not listed in the health plan drug formulary if the drugs are deemed medically necessary by a clinician pursuant to Section 1367.24.

(E) Include information on which medications are covered, including both generic and brand name.

(F) Include information on what tier of the plan's drug formulary each medication is in.

(c) For purposes of this section, "formulary" means the complete list of drugs preferred for use and eligible for coverage under a health care service plan product and includes the drugs covered under the pharmacy benefit of the product.

CA Health and Safety Code, Article 4.5 Right to Try Act

https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=104.&title=&part=5.&chapter=6.&article=4.5.

Section 111548

This article shall be known and may be cited as the Right to Try Act.

Section 111548.1

For purposes of this article, unless the context otherwise requires, the following definitions shall apply:

(a) "Consulting physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act who performs all of the following:

(1) Examines the qualified individual and his or her relevant medical records.

(2) Confirms, in writing, the primary physician's diagnosis and prognosis.

(3) Verifies, in the opinion of the consulting physician, that the eligible patient is competent, acting voluntarily, and has made an informed decision.

(b) "Eligible patient" means a person who meets all of the following conditions:

(1) Has an immediately life-threatening disease or condition.

(2) Has considered all other treatment options currently approved by the United States Food and Drug Administration.

(3) Has not been accepted to participate in the nearest clinical trial to his or her home for the immediately life-threatening disease or condition identified in paragraph (1) within one week of completion of the clinical trial application process, or, in the treating physician's medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient's current condition and stage of disease.

(4) Has received a recommendation from his or her primary physician and a consulting physician for an investigational drug, biological product, or device.

(5) Has given written informed consent for the use of the investigational drug, biological product, or device, or, if he or she lacks the capacity to consent, his or her legally authorized representative has given written informed consent on his or her behalf.

(6) Has documentation from his or her primary physician and a consulting physician attesting that the patient has met the requirements of this subdivision.

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(c) "Health benefit plan" means a plan or program that provides, arranges, pays for, or reimburses the cost of health benefits. "Health benefit plan" includes, but is not limited to, a health care service plan contract issued by a health care service plan, as defined in Section 1345, and a policy of health insurance, as defined in Section 106 of the Insurance Code, issued by a health insurer.

(d) "Immediately life-threatening disease or condition" means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months.

(e) "Investigational drug, biological product, or device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial approved by the United States Food and Drug Administration, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.

(f) "Primary physician" means a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act.

(g) "State regulatory board" means the Medical Board of California or the Osteopathic Medical Board of California.

(h) (1) "Written, informed consent" means a written document that has been approved by the primary physician's institutional review board or an accredited independent institutional review board, is signed by an eligible patient, or his or her legally authorized representative when the patient lacks the capacity to consent, and attested to by the patient's primary physician and a witness that, at a minimum, does all of the following:

(A) Explains the currently approved products and treatments for the immediately life-threatening disease or condition from which the patient suffers.

(B) Attests to the fact that the patient, or when the patient lacks the capacity to consent his or her legally authorized representative, concurs with the patient's primary physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.

(C) Clearly identifies the specific proposed investigational drug, biological product, or device that the patient is seeking to use.

(D) Describes the potentially best and worst outcomes of using the investigational drug, biological product, or device and describes the most likely outcome. This description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment. The description shall be based on the primary physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.

(E) Clearly states that the patient's health benefit plan, if any, and health care provider are not obligated to pay for the investigational drug, biological product, or device or any care or treatments consequent to use of the investigational drug, biological product, or device.

(F) Clearly states that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.

(G) Clearly states that in-home health care may be denied if treatment begins.

(H) States that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug, biological product, or device, and that this liability extends to the patient's estate, except as otherwise provided in the patient's health benefit plan or a contract between the patient and the manufacturer of the drug, biological product, or device.

(2) Written, informed consent for purposes of this article shall be consistent with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).

Section 111548.2

(a) Notwithstanding Section 110280, 111520, or 111550, a manufacturer of an investigational drug, biological product, or device may make available the manufacturer's investigational drug, biological product, or device to an eligible patient pursuant to this article. This article does not require that a manufacturer make available an investigational drug, biological product, or device to an eligible patient.

(b) A manufacturer may do both of the following:

(1) Provide an investigational drug, biological product, or device to an eligible patient without receiving compensation.

(2) Require an eligible patient to pay the costs of, or associated with, the manufacture of the investigational drug, biological product, or device.

(c) (1) This article does not expand the coverage provided under Sections 1370.4 and 1370.6 of this code, Sections 10145.3 and 10145.4 of the Insurance Code, or Sections 14087.11 and 14132.98 of the Welfare and Institutions Code.

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(2) This article does not require a health benefit plan to provide coverage for the cost of any investigational drug, biological product, or device, or the costs of services related to the use of an investigational drug, biological product, or device under this article. A health benefit plan may provide coverage for an investigational drug, biological product, or device made available pursuant to this section.

(d) If the clinical trial for an investigational drug, biological product, or device is closed due to the lack of efficacy or for toxicity, the investigational drug, biological product, or device shall not be offered. If notice of closure of a clinical trial is given for an investigational drug, biological product, or device taken by a patient outside of a clinical trial, the manufacturer and the patient's primary physician shall notify the patient of the information from the safety committee of the clinical trial.

(e) If an eligible patient dies while being treated by an investigational drug, biological product, or device made available pursuant to this article, the patient's heirs and health benefit plan, except to the extent the plan provided coverage pursuant to paragraph (2) of subdivision (c), are not liable for any outstanding debt related to the treatment or lack of insurance for the treatment.

Section 111548.3

(a) Notwithstanding any other law, a state regulatory board shall not revoke, fail to renew, or take any other disciplinary action against a physician's license based on the physician's recommendation to an eligible patient regarding, or prescription for or treatment with, an investigational drug, biological product, or device if the recommendation or prescription is consistent with protocol approved by the physician's institutional review board or an accredited independent institutional review board.

(b) The physician's institutional review board or an accredited institutional review board shall biannually report the following information to the State Department of Public Health, the Medical Board of California, and the Osteopathic Medical Board of California:
(1) The number of requests made for an investigational drug, biological product, or device.
(2) The status of the requests made.
(3) The duration of the treatment.
(4) The costs of the treatment paid by eligible patients.
(5) The success or failure of the investigational drug, biological product, or device in treating the immediately life-threatening disease or condition from which the patient suffers.
(6) Any adverse event for each investigational drug, biological product, or device.

(c) A state agency shall not alter any recommendation made to the federal Centers for Medicare and Medicaid Services regarding a health care provider's certification to participate in the Medicare or Medicaid program based solely on the recommendation from an individual health care provider that a patient have access to an investigational drug, biological product, or device.

(d) A violation of this section shall not be subject to Chapter 8 (commencing with Section 111825).

SB No. 159 Chapter 532:
An Act to Add Section 1342.74 to the Health and Safety Code Relating to HIV Prevention

Section 4

1342.74

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1342.74.

Section 1342.74 is added to the Health and Safety Code, immediately following Section 1342.73, to read:

(a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).
(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

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(c) A health care service plan shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.
(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.

Section 5.

10123.1933

https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=10123.1933&lawCode=INS

Section 10123.1933 is added to the Insurance Code, immediately following Section 10123.1932, to read:

(a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).
(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.
(b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis.
(c) Notwithstanding subdivision (b), a health insurer shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

State Market Plan Enhancements

None

Covered Benefits

Important Note: Covered benefits are listed in *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits* sections. Always refer to the *Federal/State Mandated Regulations* and *State Market Plan Enhancements* sections for additional covered services/benefits not listed in this section.

Members may have supplemental outpatient prescription drug benefit. Refer to the member's EOC/SOB to determine coverage eligibility.

Injectable drugs

- **Intravenous Infusion therapy**: Therapeutic administration of drugs or other prepared or compounded substances by the intravenous route (includes chemotherapy) when provided as part of a treatment plan and authorized by the member's primary care physician/Network Medical Group or UnitedHealthcare
  Note: The infusions must be administered in the member's home, network Physician's office ambulatory/outpatient infusion center or in an institution such as board and care, custodial care, or assisted living facility that is not a Hospital or institution mainly engaged in providing Skilled Care Services or Rehabilitation Services.
- **Outpatient Injectable Medications** include those drugs or preparations which are not usually self-administered and which are given by the Intramuscular or Subcutaneous routes when administered as part of a Physician's office visit and when not otherwise limited or excluded (e.g., insulin, certain immunizations, infertility drugs, birth control or off-label use of covered injectable medications).
  Note: The medications must be obtained through a Network Provider, the Member's Network Medical Group, or UnitedHealthcare-Designated Pharmacy and may require prior authorization by UnitedHealthcare. Refer to the Benefit Interpretation Policy titled Preventive Care Services for a description of immunizations covered as preventive care.

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- **Growth Hormone Therapy/Injections:**
  - **UnitedHealthcare Benefits Plan of California**: Growth hormone therapy is covered when medically necessary.
  - **Signature Value:** Human growth hormone injections for the treatment of idiopathic short stature only when determined medically necessary by a UnitedHealthcare Medical Director or designee .
- **Self-injectable Medications** are defined as those drugs which are medically necessary and which are either generally self-administered by the Subcutaneous route regardless of the frequency of administration, or by the Intramuscular route at a frequency of one or more times per week (except insulin)
  Note:
  - The medications (except insulin) must be prescribed by a Network Provider, as authorized by the member's Network Medical Group or by UnitedHealthcare. Self-Injectable medications must be obtained through a Network Provider, through the member's Network Medical Group or UnitedHealthcare-Designated Pharmacy/specialty injectable vendor and may require prior authorization by UnitedHealthcare. A separate Co-payment applies to all self-injectable medications for a 30 day supply (or for the prescribed course of treatment if shorter), whether self-administered or injected in the Physician's office, and is applied in addition to any office visit Co-payment or Deductible.
  - Refer to the Benefit Interpretation Policy titled Weight Gain or Weight Loss Programs for coverage information for self-injectable weight loss medications.

Off-Label Drug Use

Off-label drug use, which means the use of a drug for the purpose that is different from the use for which the drug has been approved by the FDA including off-label self-injectable drugs only when all of the following criteria are met:

- The drug is approved by the U.S. Food and Drug Administration (FDA) (for label usage);
- The drug is prescribed by a network provider for the treatment of a life-threatening condition or for a chronic and seriously debilitating condition;
- The drug is medically necessary to treat the condition;
- The drug has been recognized for treatment of the life-threatening or chronic and seriously debilitating condition by one of the following:
  - The American Hospital Formulary Service Drug Information,
  - One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:
    - The Elsevier Gold Standard's Clinical Pharmacology;
    - The National Comprehensive Cancer Network Drug and Biologics Compendium;
    - The Thompson Micromedex DRUGDEX System, or
  - It is recommended by two articles from major peer-reviewed medical journals that present data supporting the proposed Off-Label Drug Use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal;
- The drug is covered under the member's injectable drug benefit described in the outpatient benefits section of the member's EOC.

Tobacco Cessation Medications

Tobacco cessation medications that are FDA approved including (both over-the-counter and prescription) for a 90-day treatment plan are covered at zero cost share when prescribed and prior authorized. In addition you must take part in tobacco cessation counseling sessions as described in the EOC (Refer to the member's EOC/SOB)

For more information about the tobacco cessation program, contact the Customer Service department at 1-800-624-8822, or visit the UnitedHealthcare website.

Not Covered

Outpatient drugs and prescription medications, except when listed as covered or not covered or when covered under the member's Supplemental Outpatient prescription benefit. Refer to the member's EOC/SOB to determine coverage eligibility.

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Policy History/Revision Information

Date	Summary of Changes
07/01/2023	**Covered Benefits** ***Injectable Drugs*** ● Added instruction to refer to the Benefit Interpretation Policy titled *Weight Gain or Weight Loss Programs* for coverage information for self-injectable weight loss medications **Supporting Information** ● Archived previous policy version BIP098.M

Instructions for Use

Covered benefits are listed in three (3) sections: *Federal/State Mandated Regulations*, *State Market Plan Enhancements*, and *Covered Benefits*. All services must be medically necessary. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the member's Evidence of Coverage (EOC)/Schedule of Benefits (SOB). If there is a discrepancy between this policy and the member's EOC/SOB, the member's EOC/SOB provision will govern.

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