



August 2, 2019

To Whom It May Concern,

As a professional in the field of hepatitis B science and medicine, I have been asked to comment on the use of TAF (tenofovir alafenamide), sold as Vemlidy (Gilead, Foster City, CA), in general as well as recent cases of denial at multiple sites in the U.S. by various insurance companies with events that include removal from formularies with patients being redirected to other medications after being prescribed TAF.

The majority of hepatitis B virus (HBV)-infected patients require life-long therapy, but there are long-term safety concerns with use of first-line oral agents tenofovir disoproxil fumarate (TDF) and entecavir. In two industry-funded phase III trials, researchers investigated the effectiveness and safety of the novel prodrug, TAF (tenofovir alafenamide) to evaluate toxicity compared with TDF as well as efficacy.

In both studies, researchers randomized HBV-infected patients to receive oral TAF 25 mg or TDF 300 mg once daily in a 2:1 ratio. One study involved 875 patients who were positive for hepatitis B e antigen (HBeAg+) and the other involved 426 patients who were HBeAg-negative. All patients also received a placebo matching the unassigned treatment. The primary endpoint was the proportion of patients with HBV DNA level <29 IU/mL at week 48 of treatment. The prespecified noninferiority margin was 10%, and prespecified safety endpoints were bone and renal measures at week 48.

Among HBeAg-positive patients, the primary endpoint was achieved in 64% of patients receiving TAF compared with 67% in those receiving TDF, which was within the noninferiority margin. Among the HBeAg-negative patients, these rates were 94% and 93%, respectively, which was also within the noninferiority margin. Regarding safety endpoints, patients receiving TAF had smaller mean decreases in bone mineral density in hip and spine compared with patients receiving TDF. HBeAg-positive patients receiving TAF had a lower mean increase in creatinine compared with those receiving TDF, but the mean



increase was similar among HBeAg-negative patients, although the TAF group had a lower mean decrease in creatinine clearance versus the TDF group.

Taken together, therefore, it is my own individual professional judgment to support the use of TAF for patients as a primary choice for patient instead of TDF, due to the more favorable renal and bone profile, unless there are circumstances that would reason against TAF use in that individual. The cost of TAF is the same as TDF according to WAC data on the internet and information obtained from Gilead.

Please refer to AB 974, below my signature line, for the current California state law that requires continuity of care for patients on a prescribed medication.

Please contact me if you need additional information about the treatment of hepatitis B.

Sincerely,

A handwritten signature in black ink that reads "Robert G. Gish M.D." in a cursive script.

Robert G Gish MD
Principal
Robert G Gish Consultants LLC

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University of Nevada Las Vegas School of Medicine

Medical Director
Hepatitis B Foundation



BILL NUMBER: AB 974 AMENDED

BILL TEXT

AMENDED IN SENATE JUNE 3, 1998

AMENDED IN SENATE APRIL 23, 1998

AMENDED IN SENATE JULY 22, 1997

AMENDED IN SENATE JULY 10, 1997

AMENDED IN ASSEMBLY APRIL 16, 1997

INTRODUCED BY Assembly Member Gallegos

(Principal coauthor: Senator Leslie)

(Coauthors: Assembly Members Alquist, Aroner, Bordonaro, Cardoza,
Cunneen, Kuehl, Machado, Murray, and Wayne)

(Coauthor: Senator Watson)

FEBRUARY 27, 1997

An act to add Sections 1363.01, 1367.20, and 1367.22 to the Health
and Safety Code, relating to health care service plans.



LEGISLATIVE COUNSEL'S DIGEST

AB 974, as amended, Gallegos. Health care service plans:
prescription drug benefits.

Under existing law, the Knox-Keene Health Care Service Plan Act of 1975, health care service plans are regulated by the Department of Corporations. Willful violation of the act is a crime.

Existing law requires health care service plans to furnish services in a manner providing continuity of care and to be able to demonstrate to the department that medical decisions are rendered by qualified medical providers, unhindered by fiscal and administrative management.

This bill would require, for health care service plan contracts covering prescription drug benefits issued, amended, or renewed on or after July 1, 1999, that benefits shall not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that it is appropriately prescribed, and is considered safe and effective for treatment. It would prohibit construing this provision as precluding the prescribing provider from prescribing another drug that is covered by the plan and is medically appropriate. It would also prohibit construing this provision to prohibit generic drug substitutions, pursuant to specified existing law.



Existing law prohibits any plan from being 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.

This bill would provide that coverage for those different-use drugs is subject to those provisions of existing law and not ~~by~~ to this bill.

The bill would also require every health care service plan that covers prescription drug benefits to comply with certain requirements regarding *providing* notice to enrollees regarding whether the plan uses a formulary *and providing certain information about drugs on the formulary to the public, upon request* . The bill would require plans that use a formulary to provide an enrollee or member of the public, upon request, a list of all of the drugs contained in the plan's formulary, and would require the plan to provide information, by telephone, about whether specific drugs are on the plan's formulary.

By changing the definition of a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this



act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1363.01 is added to the Health and Safety Code, to read:

1363.01. (a) Every plan that covers prescription drug benefits shall provide notice in the evidence of coverage and disclosure form to enrollees regarding whether the plan uses a formulary. The notice shall be in language that is easily understood and in a format that is easy to understand. The notice shall include an explanation of what a formulary is, how the plan determines which prescription drugs are included or excluded, and how often the plan reviews the contents of the formulary.

(b) Every plan that covers prescription drug benefits shall provide to members of the public, upon request, information regarding whether a specific drug or drugs are on the plan's formulary. Notice of the opportunity to secure this information from the plan, including the plan's telephone number for making a request of this nature, shall be included in the evidence of coverage and disclosure form to enrollees.



(c) Every plan shall notify enrollees, and members of the public who request formulary information, that the presence of a drug on the plan's formulary does not guarantee that an enrollee will be prescribed that drug by his or her prescribing provider for a particular medical condition.

SEC. 2. Section 1367.20 is added to the Health and Safety Code, to read:

1367.20. Every health care service plan that provides prescription drug benefits and maintains one or more drug formularies shall provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary of the plan by major therapeutic category, with an indication of whether any drugs on the list are preferred over other listed drugs. If the health care service plan maintains more than one formulary, the plan shall notify the requester that a choice of formulary lists is available.

SEC. 3. Section 1367.22 is added to the Health and Safety Code, to read:

1367.22. (a) A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed



and is considered safe and effective for treating the enrollee's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate for the enrollee, nor shall anything in this section be construed to prohibit generic drug substitutions as authorized by Section 4073 of the Business and Professions Code. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4059 of the Business and Professions Code, to treat a medical condition of an enrollee.

(b) This section does not apply to coverage for any drug that 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. Coverage for different-use drugs is subject to Section 1367.21.

(c) 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 plans 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.

(d) Nothing in this section shall prohibit a health care service plan from charging a subscriber or enrollee a copayment or a deductible for prescription drug benefits or from setting forth, by



contract, limitations on maximum coverage of prescription drug benefits, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the commissioner and set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIIIIB of the California Constitution.

Notwithstanding Section 17580 of the Government Code, unless otherwise specified, the provisions of this act shall become operative on the same date that the act takes effect pursuant to the California Constitution.