Use and abuse of medical necessity criteria – Health insurers' denial of the Hepatitis C drug Harvoni

By Robert S. Gianelli

Health insurance policies[1] cover medical services that are "medically necessary." Over the years, this term was been expanded to include a number of criteria used by health insurers to deny expensive but critical care. The latest example of this practice can be found in health insurers' restrictions on access to the new cure for Hepatitis C, the drug Harvoni.

Harvoni denied

On December 1, 2015 the United States Senate Finance Committee released the results of an investigation into the pricing and marketing of two break-through Hepatitis C drugs, Sovaldi and Harvoni.[2] These drugs offer a cure for the estimated 3.2 million people living in the United States with chronic Hepatitis C infection. The problem is the price – $94,500 for a 12-week course of the successor drug Harvoni. The Committee's investigation revealed that Harvoni's owner, Giliad Science Inc., set the price of the drug to maximize revenue while ignoring its impact on the drug's availability.

That a publicly traded drug company would set a high price on a new drug that can cure millions of afflicted people is neither illegal nor surprising. It is called a free-market health care system where, for better or for worse, for-profit companies seek fortune in a $3 trillion health care economy. What is surprising is the response of many health insurers.

Despite their obligation to cover Harvoni, many insurers have decided to deny it to all but the sickest Hepatitis C patients, those with liver fibrosis scores (Metavir) of F3 (severe fibrosis) or F4 (cirrhosis). This is so even though Harvoni is recommended at all stages of the disease and halts the progression of fibrosis.

In rejecting the requests of those with fibrosis scores below F3, insurers have relied on a frequently used denial basis – medical necessity. For instance, as set forth in recently filed lawsuits, Blue Cross of California, dba Anthem Blue Cross, advises the less-afflicted Hepatitis C patients that:

> After careful review of the submitted medical records the determination is denial as not medically necessary of the requested Harvoni (medication) .... We cannot approve your request because records show you do not have advanced scarring in your liver.

Blue Shield of California takes a similar approach but also limits coverage to a competing drug, Viekira Pak, which has a bigger list of side effects and contraindications. Blue Shield entered into a deal with Viekira Pak's manufacturer to buy the drug at a significant discount. Blue Shield denies coverage for the better drug, Harvoni, because it "does not meet the medically necessary diagnosis and step therapy requirements for coverage."

Expansive "medically necessary" definitions

The Harvoni denials are the latest manifestation of insurers' use of expansive definitions of "medically necessary" to limit coverage for expensive but critical care. The term is defined to include various generalized criteria such as that a service must be "safe and effective," "in accordance with generally accepted medical practice," and "cost-effective."

For instance, Blue Shield's definition of "Medically Necessary" services provides in relevant part:

1. Services which are medically necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are:
   a. consistent with Blue Shield of California medical policy;
   b. consistent with the symptoms or diagnosis;
   c. not furnished primarily for the convenience of the patient, the attending Physician or other provider; and
   d. furnished at the most appropriate level which can provided safely and effectively to the patient.

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2. If there are two or more medically necessary services that may be provided for the illness, injury or medical condition, Blue Shield will provide benefits based on the most cost-effective service.

The Blue Cross contracts define "medically necessary" services as services that are "[i]n accordance with generally accepted standards of medical practice" which, in turn, is defined as standards that are "based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors."

Most health insurers also utilize internal guidelines called "medical policies" that set forth their criteria for covering certain types of treatment. As set forth above, insurers like Blue Shield include a requirement in their medical necessity definitions that any service must be consistent with their internal medical policies.

The definitions and medical policies introduce a number of criteria that allow health insurers to make subjective rather than objective assessments about the covered nature of a given service. Those subjective assessments, in turn, are influenced by insurers' financial motives as evidenced by their positions on Harvoni.

Case law

Three cases from the 1980s address what was then fairly limited policy language regarding medical necessity.

In *Sarchett v. Blue Shield of California* (1987) 43 Cal.3d 1, the policy defined medically necessary services as those that are "reasonably intended, in the exercise of good medical practice, for the treatment of illness or injury." The question was whether the insurer must yield to the treating physician's judgment or could decide medical necessity on its own. The trial court found that the policy was ambiguous because it did not state who would make the medical necessity determination. The Supreme Court determined that another provision of the policy relating to the settlement of disputes unambiguously provided that an impartial review committee subject to an arbitrator's review would make medical necessity determinations and this controlled. (*Id.*, 43 Cal.3d at 10.) The court also rejected an argument that it was against public policy to deny coverage for services ordered by the treating physician.

Nevertheless, the court instructed that "we believe the subscriber's expectations can be best fulfilled not by giving his physician an unreviewable power to determine coverage, but by construing the policy language liberally, so that uncertainties about the reasonableness of treatment will be resolved in favor of coverage." (*Id.*)

In *McLaughlin v. Connecticut General Life Ins. Co.* (N.D. Cal. 1983) 565 F.Supp. 434, the policy required that, to be covered, services must be "essential for the necessary care and treatment of the ... sickness." The insurer argued that the plaintiffs used a cancer therapy that was not approved by the FDA making it medically unnecessary. The court found that the sparse medical necessity language "provides no clear guidance as to when and under what circumstances the policy will cover experimental and unconventional treatments like immuno-augmentative therapy." (*Id.*, 565 F.Supp. at 450.) The court determined that "'necessary care' implies that the care is in some degree beneficial to the patient." (*Id.* at 451.)

Hughes v. Blue Cross of No. Cal. (1989) 215 Cal.App.3d 832 addressed the propriety of a medical necessity declination in relation to "the medical standards of the community." The court determined that "good faith demands a construction of medical necessity consistent with community medical standards that will minimize the patient's uncertainty of coverage in accepting his physician's recommended treatment." (*Id.*, 215 Cal.App.3d at 846.)

Since these decisions, medical necessity policy provisions have been greatly expanded – as can be seen by the language quoted in the preceding section. No published California decision has addressed the meaning of such language but any decision will rely on insurance policy interpretation rules that have been clarified beginning with *AIU Ins. v. Superior Court* (1990) 51 Cal.3d 807.

It is well settled that insurance contracts are treated the same as other contracts. (*Bank of the West v. Superior Court* (1992) 2 Cal.4th 1254, 1258.) The mutual intention of the parties at the time of contracting governs interpretation and the mutual intention, if at all possible, is to be inferred solely from the terms of the contract. (*AIU Ins. v. Superior Court*, *supra*, 51 Cal.3d at 821-822.) In assessing the "plain meaning" of the terms, courts are to interpret them in their ordinary and popular sense, as a layperson would interpret them. (*Waller v. Truck Ins. Exchange, Inc.* (1995) 11 Cal.4th 1, 18.)

Additionally, if policy language is ambiguous or uncertain, it will be interpreted according to the reasonable expectations of the insured. If that expectation cannot be ascertained, the language will be construed in favor the insured. (*Bank of the West, supra*, 2 Cal.4th at 1264-1265.)

There are, however, exceptions to the construction of plain language in the insurance context. Exclusions considered unusual or unfair cannot be enforced unless brought to the insured's attention and explained. (*Haynes v. Farmers* (2004) 32

Cal.4th 1198, 1210-1211.) Additionally, if policy language is clear but would render the coverage illusory, it is construed in a manner the insured would reasonably expect. (*Safeco Ins. Co. of America v. Robert S.* (2001) 26 Cal.4th 758, 765-766.) And although policy language may be plain and clear in isolation, it may be ambiguous when read in context of the policy as a whole and the circumstances of the case. (*MacKinnon v. Truck Ins. Exchange* (2003) 31 Cal.4th 635, 652.)

Medical necessity criteria misconstrued and misapplied

Sarchett v. Blue Shield of California, supra, makes clear that insurers are allowed to determine whether a service is medically necessary. But this determination must be made in an objective way based upon identifiable and discernable standards. (*Sarchett, supra*, 43 Cal.3d at 10; *Hughes v. Blue Cross of No. Cal., supra*, 215 Cal. App.3d at 846.) Unlike exclusions describing a certain type of treatment (e.g., custodial care or dental care), medical necessity provisions using over-generalized standards that insurers can interpret in a subjective fashion do not provide an objective test.

Insurers' decisions to limit Harvoni under the guise of medical necessity provide a case in point. While insurers have denied Harvoni to patients with liver fibrosis scores below F3 on the basis that the drug is "not medically necessary" for them, the letters to the insureds do not explain why that is the case. Industry documents indicate that insurers have relied on a set of guidelines published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. While those guidelines do reference the prioritization of new Hepatitis C drugs for patients with F3 and F4 stage fibrosis, they do so relative to when "resources limit the ability to treat all infected persons immediately as recommended ...."[3] Absent this limitation, the guidelines state that the drugs are "best administered in the early course of the disease before fibrosis progression and the development of complications ...."[4]

Harvoni has been available and its cost does not threaten the solvency of any insurer. The end result is that Blue Cross, Blue Shield and other insurers have limited coverage for Harvoni based upon profit concerns, not on some lack of consensus of medical opinion regarding its beneficial use for millions of Hepatitis C patients. This is not a proper medical necessity denial basis. (*Hughes v. Blue Cross of No. Cal., supra*, 215 Cal.App.3d at 846.)

Even if there was some credibility to the position that Harvoni should not be provided to the less afflicted, there is no reasonable method for an insured to assess that from the policy language. For example, Blue Cross's medical necessity provision references a generally accepted medical practice standard that is further defined as based upon "credible" peer reviewed articles that are themselves "generally recognized" by the "relevant" medical community, specialty societies, etc. This language creates various levels of uncertainty requiring that it be construed in accordance with the insured's reasonable expectations and, ultimately, a finding of coverage. "[U]ncertainties about the reasonableness of treatment will be resolved in favor of coverage." (*Sarchett v. Blue Shield of California, supra*, 43 Cal.3d at 10.)

Insurers have limited coverage for Harvoni based upon profit concerns, not on some lack of consensus of medical opinion regarding its beneficial use for millions of Hepatitis C patients. This is not a proper medical necessity denial basis.

There is also a substantial argument that the subjectivity infused in the medical necessity determination triggers one or more of the plain language exceptions. Allowing an insurer with a financial interest to pick and choose self-serving medical articles would support a denial in almost any circumstance rendering the language illusory. (*Safeco Ins. Co. of America v. Robert S., supra,* 26 Cal.4th at 765-766 [interpretation of illegal acts exclusion as applying to the violation of any law, not just criminal laws, could be used to negate coverage in almost any circumstance].)

And policy language that includes the insurer's internal medical policies as a separate medical necessity criterion is itself vague and ambiguous. The medical policy is not disclosed and its content is, nevertheless, the product of a subjective and biased determination. (*Potter v. Blue Cross Blue Shield of Michigan* 2013 WL 4413310 (E.D. Mich. March 30, 2013) [finding medical policy "internally inconsistent, ambiguous, and most fatally, not supported by the evidence in the record."].)

Blue Shield's additional "medically necessary" requirement that Hepatitis C patients use an alternative drug because it is more cost-effective for Blue Shield raises another troubling issue. The alternative drug, Viekira Pak, carries substantially more side effects and contraindications than Harvoni. Indeed, on October 22, 2015, the FDA warned that Viekira Pak "can cause serious liver injury mostly in patients with underlying advanced liver disease.... [W]e are requiring the manufacturer to add new information about this safety risk to the drug labels."[5] Because Blue Shield already limits treatment to patients with F3 or F4 liver fibrosis scores, Viekira Pak may present them with higher risks.

Medical necessity determinations should not disadvantage insureds by forcing them to face higher medical risks. If a treating physician recommends Harvoni as the best drug for a patient, the insurer should not be allowed to elevate its financial interests over the insured's interest to be protected from risk of side effects, further doctor visits, etc. The insurer is duty bound to "give at least as much consideration to the welfare of its insured as it gives to its own interests. (*Egan v. Mutual of Omaha Ins. Co.* (1979) 24 Cal.3d 809, 818.) ■

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[1] Commercial health coverage is provided in California by both insurance companies regulated by the Department of Insurance and by health care service plans regulated by the Department of Managed Health Care. For simplicity, this article refers to the providing companies as "insurers" and their products as "policies."

[2] *The Price of Sovaldi and Its Impact on the U.S. Health Care System*, United States Senate Finance Committee, Dec. 2015.

[3] *Hepatitis C Guidance: AASLD-IDA Recommendations for Testing, Managing, and Treating Adults Infected With Hepatitis C Virus*, Hepatology, Vol. 62, No. 3, 2015, p. 935.

[4] *Id.*

[5] FDA Safety Announcement dated Oct. 22, 2015.