Chapter 9

Financial Access to Unconventional Cancer Treatments

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Chapter 9

Financial Access to Unconventional Cancer Treatments

INTRODUCTION

How much unconventional cancer treatments cost and whether health insurance policies cover these costs are important to patients, their families, proponents of unconventional treatments, and third-party payers.[1] Insurers tend to stipulate that coverage of medical treatments is dependent on the treatment's being 'reasonable and necessary,' or 'medically necessary." Generally, to fulfill these terms the treatment must be accepted as effective and safe. Medicare, for instance, reasons that if the treatment is not accepted (by the medical profession) as effective then it is not reasonable to use the treatment. Third-party payers treat most unconventional cancer treatments as not having been shown to be medically efficacious in the treatment of cancer and that some, such as laetrile, have been shown to be ineffective. Insurers will not willingly pay for treatments that are not generally accepted as effective. On the other hand, patients and proponents often contend that unconventional treatments do have a beneficial medical effect on the patient, and therefore should be covered by the patient's health insurance.

At the core of this dispute is the issue of the safety and efficacy of the various unconventional cancer treatments. Patients and advocates of unconventional cancer treatments typically rely on subjective evidence, often the patients' perceptions of their post-treatment physiologic state, to determine treatment efficacy. Even if the size of the tumor has not decreased, patients may feel that the treatment has arrested further growth of the tumor, or has enabled them to enjoy a better quality of life. Patients previously treated with conventional therapies may believe the unconventional cancer treatment was more successful in restoring their health. Many individuals who believe they have benefited from unconventional treatments do not seethe charges for their treatment as excessive or unfair, and often expect that their health insurance will reimburse them for all expenses.

Third-party payers, however, rely on the opinions of physicians and scientists from the mainstream medical community regarding the safety and efficacy of medical treatments. If the physician reviewer is not already familiar with the treatment, the third-party payer will look for information from clinical trials, peer-reviewed medical literature, and duplication of results by other investigators. As shown in chapters 2 through 6, little of this sort of information currently exists for unconventional treatments. Although proponents of unconventional treatments often point to case histories or other descriptive studies as proof of safety and efficacy, these data rarely meet the standards of evidence required by the third-party payers and their physician reviewers. Reimbursement for unconventional cancer treatments is thus rarely, if ever, recommended.

The question of reimbursement for unconventional cancer treatments is most important when treatment charges are high and patients find it difficult to pay for them from personal funds. Critics of unconventional cancer treatments often claim that the treatments are very costly, while proponents contend that unconventional treatment charges generally are lower than those for conventional therapies. However, virtually no research has been conducted on the charges for unconventional cancer treatments, so it is not possible to determine how much cancer patients pay for them. Third-party payers are also concerned about charges for unconventional treatments, since they unknowingly may reimburse patients for these treatments.

Cancer patients who use unconventional treatments as their primary treatment are most significantly affected by the insurers' reticence to reimburse the costs of unconventional treatments. But there is a broader implication for the general practice of medicine. By refusing payment, insurers affect the use of unconventional treatments as adjuncts to conventional treatment. For instance, a physician might be less likely to prescribe a psychological treatment that the patient's insurance will not cover.[2] It is likely, therefore, that the present reinibursement

[2]Blue Cross and Blue Shield plans, for instance, generally do not cover the costs of learning visualization or imaging for relief of pai(637).

[3]For unconventional cancer treatments, this would most likely consist of eating only organically raised meats and produce, adding vitamin and mineral dietary supplements, or both.

system acts as an impediment to the incorporation of any unconventional approach into a conventional treatment regimen (8).

This chapter explores some of the issues related to charges and reimbursement for unconventional cancer treatments. Topics include a descriptive discussion of treatment charges; an estimate of total initial treatment charges for certain types of treatment or selected clinics; third-party payer criteria for reimbursement of medical services; the process of claims evaluation; court cases involving denials of reimbursement; and fraudulent insurance claims associated with unconventional cancer treatments.

CHARGES FOR UNCONVENTIONAL CANCER TREATMENTS

Cancer patients may receive unconventional treatments in many different settings. Some patients make office visits to a local practitioner, others travel within the United States to a hospital or practitioner's office for outpatient treatments, and certain individuals choose inpatient or outpatient treatment in Mexico, the Caribbean, Europe, or Asia. In this chapter, OTA has chosen one word, "clinic," to refer to any setting in which an unconventional cancer treatment is provided. With the exception of one mail-order treatment clinic, the word clinic encompasses physicians' offices; institutions that provide services, such as surgical, medical, laboratory, and diagnostic services that are typically found in U.S. accredited hospitals, and that treat both inpatients and outpatients; and institutions whose services are not as inclusive as those found in U.S. accredited hospitals, but that do offer certain services to inpatients, outpatients, or both.

Variations among charges occur both between clinics that offer different types of treatment (such as nutritional or pharmacologic) and among clinics offering similar treatments. As with any medical service, charges may vary among patients who receive similar treatments due, in part, to differences in the individual's health status. The stage of the disease, the patient's response to treatment, and the presence of other serious illnesses that must be treated concurrently could affect the intensity and duration of use of medical services. Factors most often causing variation among clinic charges for unconventional cancer treatments include: the breadth of services available (especially laboratory and diagnostic testing facilities) at the clinic; the type of treatment (e.g., nutritional, pharmacologic, herbal) that is offered; the services that are covered under the charges for an "office visit" or "cancer treatment program' the setting (inpatient or outpatient) in which treatment is delivered; and the length of initial and followup treatment.

Other factors, not unique to unconventional cancer treatment clinics, unpredictably affect treatment expenses. For example, if the treatment includes a change in dietary habits[3], the patient's food bill may increase. Those patients who are treated at outpatient clinics away from their home city must pay hotel, food, and transportation expenses for the duration of their treatment, which can range from a few days to several months or more. If family members accompany the patient during treatment (which is encouraged or required by some clinics), their travel and subsistence could be considered part of total treatment expenses for the individual as well.

OTA reviewed patient information brochures and Third Opinion, a directory of alternative cancer treatment centers (289). An OTA contractor subsequently contacted each clinic and verified and in some cases updated the information compiled on charges, duration of treatment, followup treatment, and at-home followup treatment programs. The information presented in this section was current as of May 1988, and reflects charges at 44 clinics[4] in the United States, Canada, and Mexico; this may not be representative of all available treatments. Clinics were only classified as "treatment clinics" if the patient brochures advertised treatment for cancer, or if the clinic was listed under the heading 'Treatment Centers' in Third Opinion. Since the time this information was gathered, charges may have changed, clinics may have closed, and some new clinics may have opened. This section should be only regarded as a descriptive review of charges at some unconventional cancer treatment clinics.

[3]For unconventional cancer treatments, this would most likely consist of eating only organically raised meats and produce, adding *vitamin* and mineral dietary supplements, or both.

[4]Sixty clinics were initially identified through patient brochures and *Third Opinion,* however, 16 clinics could not be included in the final study because they were closed, could not be contacted, chose not to answe OTA's inquiries, or provided incomplete information.

Presentation of Charges

Unconventional cancer treatment clinics usually present their charges in one of three ways. Some clinics charge for a "cancer treatment program," typically lasting about 3 weeks, although some may extend up to 6 or 8 weeks. The single charge generally covers physician visits, medications, room and board (if given in an inpatient setting), and certain services (such as colonic therapy) that are intrinsic to the treatment. Charges for all laboratory and diagnostic tests, or for any "medications" from the clinic that the patient continues to use at home following discharge, may also be considered part of this charge.

Other clinics charge patients by a given time period-per day, week, month, or year of treatment—and may or may not include charges for laboratory and diagnostic tests, at-home medications, etc.

The remaining clinics charge patients per treatment "component.' Separate charges are listed for physician office visits, laboratory and diagnostic testing, and for each injection or infusion. Some clinics indicate the number of components that a patient typically receives during the course of treatment. Total expenses for these treatments may be more difficult to estimate than for clinics that charge by a given time period or for a set treatment program.

Description of Charges

In the following sections, the range of charges and treatments is given by category of treatment, using the same categories as in previous chapters wherever possible. No compilation of actual patient expenses for treatment at the various clinics exists to which the charges, as reported by the clinics and presented here, can be compared. Charges for some specific patients are known, and in some cases they fall within the range given by clinic information, and in other cases they are considerably greater than expected. The general lack of validation of these figures should, therefore, be kept in mind.

Biologic

while other clinics offering biologic treatments might exist, OTA found information on only two, one located in the Bahamas and one in the United States; both offer outpatient treatment only. Treatment at one clinic lasts approximately 10 days and the charges range from $4,500 to $5,000. The other clinic charges $10,000 for 6 to 8 weeks of treatment. Treatment at both clinics includes at-home followup treatment, although neither provides information on the frequency or duration of such followup. Charges for the followup program at the first clinic are $400 to $600 per month, and $200 per month at the second clinic. The followup treatment charges at the first clinic may be reduced if the patient responds positively to treatment. The first clinic also recommends that the patient return to the clinic for a 2-day followup visit after 1 month, 3 months, 6 months, and 1 year. Charges for these visits vary. The second clinic recommends return visits of about 1 week every 3 or 6 months.

Herbal

Herbal treatments are available from a Mexican clinic and by air mail from Canada. The Mexican clinic offers outpatient treatment for 1 to 3 days and charges $3,500 for lifetime treatment. Laboratory charges, which average $450 to $850, are extra. Patients may return for followup visits (schedule unspecified). The treatment includes nutritional supplements and dietary changes which patients continue at home.

The second herbal treatment is a tonic that maybe ordered from Canada. Patients are charged $10 (Canadian dollars) for a 16-ounce bottle, and during the first 2 years, patients may use 23 to 46 bottles. After 2 years, the daily dose may decrease, although treatment may continue for 6 or 7 years. No clinic offers this treatment. Orders are relayed through the Canadian department of Health and Welfare to the private Canadian company that manufactures the tonic, and the tonic is then sent directly to patients.

Pharmacologic

One U.S. clinic offering a pharmacologic treatment charges by component. The cost of a visit ranges from $60 to $125, depending on whether it is a first visit, office visit, or hospital visit. In addition, the charge for the basic cancer program is $45 per "treatment, ' with an average of four to seven outpatient treatments per day for 2 to 4 weeks (this totals $2,520 to $8,820). A second program, for "high dose' treatment, is administered every other day and costs $685 per treatment. It is unclear if patients could receive both treatments concurrently. Charges for followup visits are $60 for an office visit, plus treatment charges, which vary by patient.

A downpayment of $3,000 to $5,000 is required before starting treatment at this clinic.

Pharmacologic and Biologic

A combination of pharmacologic and biologic treatments is offered at two clinics, one in Mexico and one in the United States. The U.S. clinic has outpatient treatment only, and the Mexican clinic treats both outpatients and inpatients. Charges range from $5,100 to $9,000 for 3 weeks of treatment at the Mexican clinic. There are two types of followup treatment provided by the Mexican clinic: 1) referral to specific physicians in the United States, and 2) treatment materials for which patients are charged $300 to $1,500 per month. The U.S. clinic charges $375 for 6 months of treatment and approximately $250 per month for supplements. The initial outpatient visit lasts 1 to 3 days. The only reference to follow-up says that it is prescribed "as needed" and that it costs approximately $100.

Pharmacologic and Nutritional

Eleven clinics, two in Mexico and nine in the United States, use a combined pharmacologic and nutritional approach. Both Mexican clinics provide inpatient treatment, and the U.S. clinics only offer outpatient treatments. Four U.S. clinics charge $1,500 to $4,500 for 3 to 4 weeks of treatment and a fifth clinic, located in Mexico, charges $7,500 for 3 weeks of treatment. The second Mexican clinic charges $1,500 per week and recommends 2 to 8 weeks of treatment; lab fees, which are extra, average $400 to $500 per week. One U.S. clinic charges by the month: the first month costs $1,500, and each month thereafter is $300, although this clinic did not provide an estimate of the total initial treatment period. Another U.S. clinic charges $4,000 to $5,000 for 1 year of treatment. The remaining three clinics in this category charge by components. Office visits range from $50 to $280; initial evaluations range from $100 to $280.

Some information on followup visits was available for eight U.S. clinics. Charges at five clinics range from $20 to $200 for a followup visit. Only the clinic with charges at the upper end of this range indicated the average length of these visits, approximately 1 to 2 days. Three of these five clinics also indicated the frequency of follow-up visits, which are recommended at periods ranging from 2 weeks to 4 months following initial treatment. A sixth clinic advises weekly, monthly, or bimonthly followup visits, and includes the charges for these visits in its initial treatment charges. Two clinics simply indicate that charges for and the frequency of followup visits vary.

Seven clinics, including both Mexican clinics, provided information on at-home treatment programs. No clinic estimated the duration of at-home followup treatment, although two clinics indicated that their treatment in part constituted a lifestyle change. Six clinics listed charges for followup supplements or medications, ranging from $50 to $300 per month.

Nutritional and Biologic

One U.S. clinic offers a nutritional and biologic treatment, given on an outpatient basis. This clinic does not estimate the length of the initial treatment period. The initial office visit costs $200, with additional charges of $80 to $350 for lab tests. The clinic recommends that patients return for a followup visit, which costs $55, after 2 to 3 months. A recommended annual "re-evaluation" costs $200. No at-home followup program is described.

Nutritional and Psychological

One U.S. clinic offers an outpatient treatment that combines nutritional and psychological components. Patients may receive 1 to 7 days of initial treatment, which costs $325. No follow-up visits or at-home followup treatment programs are deseribed for this clinic.

Miscellaneous (Hyperthermia)[5]

One U.S. clinic provides whole-body hyperthermia to outpatients. The recommended initial program consists of 25 hyperthermia treatments over 5 weeks. Patients are charged $400 per treatment, or $10,000 for the full course. The clinic suggests that patients return for followup visits after 2 weeks, then after an additional month, then every 2 months. There is no charge for the followup visits. There is no mention of at-home followup treatment.

[5]In mainstream medicine, local or regional hyperthermia is accepted as adjunctive treatment for some cancers, along with radiotherapy, but is considered investigational in other settings (694). Whole-body hyperthermia is not an accepted modality in mainstream medicine.

Combination Treatments

Approximately half the clinics (23) for which data were available offer combinations of at least three types of treatment for cancer patients. Three such clinics are in Mexico, 4 operate in Canada, and the remaining 16 are in the United States. These clinics fall into one of three categories according to how they charge for treatments: by entire initial treatment program, by periods of time, or by initial treatment components. Few of these clinics give information on the cost of followup regimens.

Ten clinics have a set charge for the full initial treatment program. Six of these clinics (one Canadian and five U. S.) operate on an outpatient basis only, with charges and treatment periods ranging from $500 to $900 for a 1+ day course, $4,000 for 2 weeks of treatment, $4,000 to $10,000 for 3 to 6 weeks, to $3,000 to $8,000 for 1 year of treatment. Three clinics (two in Mexico and one in the United States) provide inpatient treatment. The Mexican clinics charge $6,000 to $6,500 for 3 weeks of treatment; one of these also charges $1,800 for each additional week. The third clinic offers a month-long inpatient treatment for $8,000 to $10,000.

Six clinics charge by periods of time. One accepts biweekly donations of $100 to $2,000 for outpatient treatments that last from 2 to 52 weeks. Another provides 8 to 12 weeks of treatments, at a cost of $3,600 per week, on both an inpatient and outpatient basis. A third treats patients for 3 to 4 weeks at $3,100 per week. Three weeks of outpatient treatment at a fourth clinic is estimated to cost $1,500 per week. In addition, one clinic charges $1,200 to $1,400 per day for 3 to 5 days of outpatient treatment, while another charges $400 to $700 per month for 3 to 6 months of outpatient treatment.

Seven clinics (two in Canada and five in the United States) charge by treatment component. Six of these provide treatment only on an outpatient basis; the seventh treats on an inpatient basis. Charges for office visits range from $35 to $500. The clinic with the lowest charge per office visit charges an additional $50 to $400 for treatment. The wide variation in charges for the office visit results, in part, from the different services that are considered to be part of an "office visit." For example, a few clinics include costs for diagnostic tests with the office visit charge, while others list separate charges for laboratory or diagnostic tests, which range from $5 to $600. One clinic estimates total charges for the frost office visit at $300 to $1,800.

Twelve clinics provide some information on the amount and cost of followup visits. Outpatient followup visits for four clinics last from 1 to 5 days. At another, followup consists of 8 to 10 days of inpatient treatment. Charges for these clinics range widely, from $50 for a l-day visit, to between $500 and $1,000 for 2 to 3 days of treatment, $1,200 to $l,400 per day for a 5-day visit, to $1,500 for an 8-to 10- day inpatient visit. The remaining seven clinics list charges for followup visits but do not specify the duration of the visit. Five of these clinics charge from $20 to $300 for a followup visit. One clinic does not charge for the visit itself, but does charge $140 to $225 for laboratory work. Another lists $60 as the "base' price for the visit.

The charges for at-home followup programs are available for eight clinics. Supplements range from $50 to $300 per month at five of these. Two clinics appear to charge a flat fee of $100 to $150 for the followup program. Two of the seven clinics include medication in the followup charges, while a third clinic charges an additional unspecified amount for medications.

Estimating Total Initial Treatment Expenses

Based on the above information, OTA estimated the range of expenses within each treatment type for an initial treatment program.[6] To determine the range of expenses, OTA either used the single charge for "cancer treatment programs" or estimated the expenses based on the clinics' listed charges and duration of treatment. Charges for laboratory or diagnostic services are included in the total treatment expenses only if the clinic indicated a range of such charges.

6& mentioned earlier, the "initial treatment program" refers to the treatment obtained during the period of time, as determined by the clinic, that the patient receives his or her first course of treatment. This period of time was defined as the length of time indicated by the clinic in their brochures, or under the heading "Length of Treatment/Stay" in *Third Opinion,* and checked with the clinics by the OTA contractor. These charges are presented exactly as given by the clinic, and may or may not include expenses for diagnostic services, laboratory services, or room and board. Treatment continued as part of an at-home followup program is not considered part of the initial treatment program, and therefore expenses for followup programs or visits are not included in the estimated total initial treatment charges.

Table 9-1 shows the range of charges among clinics that offer only one or an indivisible package of treatments. Charges for the two herbal treatments were lower than charges for treatments at the other three clinics. The Bio-Medical Center, offering "Hoxsey" treatment, lists charges for laboratory work, examinations, and x-rays as an additional $450 to $850. It was unclear if this was the estimated additional charge for each visit, or for lifetime treatment.

The costs of initial treatment with IAT and Antineoplastons appear to be about the same, approximately $10,000. However, it is unclear if patients at Burzynski's clinic can receive the "high-dose treatment" and the standard Antineoplaston treatment in combination; if this is possible, initial treatment charges could then approach $20,000. The cost might also vary depending on the number of office or hospital visits made by a patient during the initial treatment period; a large number of visits could substantially increase the total initial treatment costs.

Table 9-2 summarizes the range of initial total treatment expenses at 25 clinics offering combinations of treatments.[7] Expenses range widely for initial treatment programs, from $100 to $52,000 for combination treatments, and from $1,500 to $16,000 in the pharmacologic and nutritional category. Clinics with lower charges often only treat outpatients; a patient's actual expenses for treatment could be higher after paying for room and board.[8]

Quality of Charge Information

It is impossible to estimate total initial treatment expenses based on the information given in some clinic brochures. Clinics that itemize charges are the most difficult; not only do the length and intensity of treatment vary, but clinics often do not report the typical range of treatment components that patients receive. Itemized charges may make a clinic's treatment appear less expensive than treatment at a clinic that charges a single fee for the initial treatment program. For example, Stanislaw Burzynski's clinic charges $45 per treatment of Antineoplastons. However, based on the dosage information in the patient brochure, total charges for a standard regimen of Antineoplaston injections alone (not including charges for office visits and laboratory tests and diagnostic tests) could be $2,520 to $8,820 for the initial treatment period. In addition, listed itemized expenses typically include only office visits and laboratory tests; it is not always clear if there is an additional charge for the treatment itself.

Total treatment expenses for an individual patient have occasionally been reported publicly, generally during litigation over reimbursement or in articles describing a particular unconventional treatment or practitioner. One patient incurred medical bills of approximately $200,000 for 21 months of treatment that began in early 1986 at the Burzynski clinic (192). This particular patient's medical bills (nearly $9,500 per month) seem substantially higher than what would be expected from the clinic's patient information materials.

Total treatment expenses may be easier to project for clinics with a single charge or charges by periods of time. For instance, the Bio-Medical Clinic in Tijuana charges patients a lifetime fee, excluding the charges for laboratory and certain diagnostic tests. These additional expenses are estimated in the patient information materials, so patients could include them when estimating total treatment expenses. One report of total expenses for a patient who received treatment at the Gerson clinic, which charges patients on a weekly basis, suggests that total treatment expenses may be accurately predicted from this type of charge information. This particular patient received 6 months of treatment in 1984, for which he was charged $10,000 (728). As of May 1988, the predicted charges for this clinic (including separate laboratory charges) were approximately $2,000 per week for a 2- to 8-week initial treatment period. Followup treatment expenses were estimated at $50 per month. For 6 months of treatment in 1988, expenses would range from $4,250 to $16,250. This patient's expenses of $10,000 fall within the expected range.

[7] In table 9-2, expenses were not estimated for the 13 clinics that listed charges by treatment component. Nutritional and biologic treatments are not shown in this chart because the only clinic included in this category charges patients by treatment component. An additional clinic, described in the pharmacologic and nutritional section, was not included because it did not provide an estimate of the duration of treatment and it was thus not possible to extrapolate total initial treatment charges.

[8] Duration of treatment at outpatient clinics ranged from 1 day to 3 months.

Table 9-l—Total Initial Treatment Charges for Proprietary Treatments

Clinic	Treatment	Duration of initial treatment	Approximate total initial treatment charges	Clinics that charge by component: Component	Charges per component	Number of components used per week	Approximate total initial treatment charges
Immunology Researching Center	Immuno-Augmentative Therapy	6-8 weeks	$10,000				
Livingston-Wheeler Clinic	Autogenous vaccines, diet, vitamin and mineral supplements	10 days	$4,500-5,000 (includes 30 days of medicine and approximately 6 months of vaccine)				
Bio-Medical Center	Hoxsey herbal tonics and salves	Lifetime	$3,500				
Essiac	Herbal tonic[a]	52-104 weeks		16 oz. bottle	$10	.9 (first 10 days) .45 (remainder)	$230-460
Burzynski		2-4 weeks		Treatment with Antineoplastons	$ 4 5	28-49	$2,520-$8,820
				High dose treatment	$685	3-4	$4,795-9,590
				Office visit	$ 6 0	Unspecified	not given
				Hospital visit	$100	Unspecified	not given
				initial consultation	$125	Only one charge for this component	$125

[a]Patients are also instructed to take vitamin and mineral supplements; charges for these supplements have not been included, nor have charges for shipping Essiac.

SOURCE: Office of Technology Assessment, 1990.

Table 9-2—Costs of Selected Unconventional Cancer Treatments

Treatment type	For clinics reporting total initial treatment charges: Number of clinics	Range of charges	Range of length of treatment	For clinics reporting charges by time period: Number of clinics	Range of charges
Pharmacologic and biologic				1	$1,700-$3,000 per week × 5 weeks of treatment = $5,100-$9,000
P maco og and triti al		$ 500-$ 500	14-21 days at 4 clinics 3+-26 weeks at 1 clinic 1 year at 1 clinic	1	,900-$2,000 per week ×2-8 weeks of treatment =$3,800-$16,000
Nutritional and psychological	1	$325	1-7 days		
Miscellaneous-hyperthermia				1	$400 per day x at least 25 days of treatment = $10,000
Combinations—three or more treatments	o	$425-$10,000	1+ days at 2 clinics 2-6 weeks at 7 clinics 1 year at 1 clinic	11	$3,600 per week x 8-12 weeks of treatment = $28,800-$43,200 $3,100 per week x 3-4 weeks of treatment = $9,300-$12,400 $400-$700 per month x 3-6 months of treatment = $12,000-$4,200 $1,200-$1,400 per day ×3-5 days of tr me = $3,600-$7,000 $100-$2,000 biweekly (donations?) x 2-52 weeks = $100-$52,000

SOURCE: Office of Technology Assessment, 1990.

The total *treatment charges estimated by OTA (see tables 9-1 and 9-2) are higher than those reported by Cassileth and her colleagues in 1984 (177). Based on interviews with 202 patients, they determined that charges for the frost year of unconventional cancer treatment were under $1,000 for most patients and less than $500 for 50 percent of patients. However, these data sets cannot be compared directly because OTA's data differ from Cassileth's in several important ways. First, OTA only looked at charges for organizations that identified themselves as treatment clinics, and these charges may be greater than those for all available unconventional cancer treatment services. Second, charges in Cassileth's study were reported by patients, and no documentation for these self-reported data was sought. Third, Cassileth includes expenses for two types of treatment, spiritual and imagery, which were not included in OTA's analysis[9]; 87 percent of patients who used imagery and 94 percent of those using spiritual treatments spent less than $500 in the first year of treatment.*

Proponents of unconventional cancer treatments often claim that charges are generally lower than those for conventional therapies. The range of initial total treatment charges as estimated by OTA (tables 9-1 and 9-2) suggest that charges may fall both above and below initial treatment charges for conventional cancer treatments. One estimate of patient expenses for conventional cancer treatments comes from a study that used data from the Medicare Continuous History Sample File (MCHSF) (66).[10] Initial treatment charges, defined as those occurring in the first 3 months after diagnosis, ranged from $6,954 for melanoma to $14,443 for stomach cancer, with the average for all sites being $10,039. Continuing monthly expenses[11] ranged from $424 (uterine corpus) to $766 (bladder), with the average for all sites being $578. For several reasons, these numbers should not be viewed as definitive estimates of the cost of conventional cancer treatments. First, that study may underestimate expenses for conventional cancer treatment, in part because Medicare coverage does not extend to all the medical services required by a cancer patient, such as prescription drugs. In addition, estimates of costs are in 1984 dollars, so an adjustment for medical cost inflation would be needed to bring the estimate up to current dollars. It was not OTA's purpose in this report to delve into the issue of conventional treatment costs; the numbers are simply provided for a rough comparison.

Summary

Charges for unconventional cancer treatments vary from a few hundred to tens of thousands of dollars and it maybe difficult for a patient to predict actual treatment expenses. It is impossible to assess the accuracy of OTA's estimates of total initial treatment charges for unconventional cancer treatments because information provided by the clinics is not always precise, and only one other researcher has attempted to estimate charges for unconventional cancer treatments. The expenses for a single patient may be more than any of these data suggest as some patients use more than one unconventional cancer treatment (177,265). While charges at many unconventional cancer treatment clinics appear to fall below the average charges for conventional cancer treatment, patients often must pay out-of-pocket for all unconventional services (see next section), and thus unconventional treatments may incur greater economic losses for an individual.

THIRD-PARTY REIMBURSEMENT FOR UNCONVENTIONAL CANCER TREATMENTS

An ongoing debate surrounds the question of whether third-party payers should reimburse for medical expenses related to unconventional cancer treatments. Many patients are frustrated when their claims are denied. Medical services that lack data showing efficacy and safety, or are not generally accepted by the medical mainstream, may not be covered by third-party payers, even if a patient believes he or she benefited from such a service.

[9]Although there are several clinics that offer psychological treatments, including imagery, these were described as "support groups" in their brochures or in *Third Opinion,* and thus were not included in our analysis of charges.

[10]Charges for inpatient hospital stays, skilled nursing facilities, home health agencies, outpatient services, physician services, and psychiatric services were all included in the dataset. Expenses were defined as the charges to Medicare, rather than the amount reimbursed by Medicare to the physician, patient, or provider.

[11]Continuing expenses were defined as all monthly charges beginning the fourth month after diagnosis and ending with the seventh month before death, if death occurred. These expenses are probably an overestimate, since, unlike the data for initial treatment, this dataset includes charges for both cancer and non-cancer-related medical services.

Patients who receive unconventional cancer treatments may believe that their expenses will be covered, because patient information materials from many clinics claim that many or most U.S. insurance companies will reimburse patients for the medical expenses of their treatment. However, most U.S. third-party payers do not knowingly reimburse claims for unconventional cancer treatments. In some cases, the insurer may pay claims unwittingly, lose a court case and be forced to pay for treatment, or settle out of court to avoid a trial.

As with coverage for any type of treatment, the language of the insurance contract is the key determinant of whether an unconventional cancer treatment will be covered. The contract language sets the criteria that a medical service must meet before the third-party payer will reimburse any patient expenses. If a particular medical service is disallowed by name in the policy, the third-party payer is not legally obligated to reimburse the expenses of that service to the consumer. However, third-party payers cannot reasonably be expected to individually specify all of the medical services that are or are not covered by the policy; therefore they rely upon phrases such as "medically necessary' and 'reasonable and necessary, to describe what is covered. Such general language lends itself to a variety of interpretations; disputes over the interpretation of these phrases form the basis of many lawsuits against third-party payers.

The criteria *used to determine coverage and reimbursement and the sources consulted for information are other points of dispute in court cases involving unconventional cancer treatments. Although each third-party payer determines its own criteria for coverage, many consult similar sources for information. The published medical literature and the opinions of medical specialty societies, individual physician consultants, or national organizations such as the American Cancer Society (ACS), the National Cancer Institute (NCI), the American Medical Association (AMA), and the U.S. Pharmacopeial Dispensing Information (USP DI) are the main sources of information used by third-party payers. These sources provide little support for unconventional cancer treatments.*

This section describes typical contract provisions and claims evaluation practices for the major U.S. third-party payers: Medicare, Blue Cross/Blue Shield (BC/BS), and commercial carriers.

Contract Provisions Relating to Unconventional Cancer Treatment Reimbursement

Medicare

Title XVIII of the Social Security Act established Medicare, a federally-funded program that covers hospital, physician, and other medical expenses for persons 65 years of age and older, certain disabled persons, and persons with certain chronic diseases (not including cancer). The Health Care Financing Administration (HCFA), the Federal agency responsible for administering the Medicare program, writes guidelines for coverage and reimbursement. Other Federal programs, including Medicaid and the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), are influenced by Medicare coverage and reimbursement decisions (791).

The law that created Medicare prohibits payment for services or items that "are not reasonable and necessary for the diagnosis or treatment of illness or injury" (Social Security Act, Section 1862(a)1, 42 USCA 1395y (l)(A)). As interpreted by HCFA, a treatment is considered medically reasonable and necessary if it has been generally accepted by the professional medical community as effective and safe for the condition being treated.[12] Colonic irrigation, cellular therapy, and laetrile are among the medical procedures or items HCFA does not consider to be reasonable and necessary; therefore, they are not currently covered by Medicare (221).

With a few exceptions, which are discussed below, drugs and biologics must have final marketing approval from the Food and Drug Administration to be considered safe and effective and, therefore, reasonable and necessary .13 Under the laws of the Medicare program, a substance is not

[12]Part A Intermediary Letter No. 77-4, January 1977, as cited in R.D. Schwartz, and R.L. Burke, ' 'Legal Constraints on the Availability of Unorthodox Cancer Treatments: Consumer Protection View" (791).

[13]"Approved indications" refers to those medical uses for which the FDA has 'et ermined the drug is safe and effective. The drug manufacturer must present clinical data for each indication sought, that demonstrates safety and efficacy; if the manufacturer presents data for more than one medical use of the drug, more than one indication may be approved to appear on the label.

considered a' 'drug' or 'biologic' unless it is listed or approved for listing in certain drug compendia. These compendia include the U.S. Pharmacopoeia, National Formulary, U.S. Homeopathic Pharmacopoeia, AMA Drug Evaluations, or Accepted Dental Therapeutics (Sec. Sec. Act Section 1861(t), USCA 42 Section 1395(t), CCH 1223,3115, 1988). Drugs and biologics used for indications other than those approved by FDA may be covered as long as FDA has not ruled that such use is unapproved specifically; and as long as other reimbursement criteria are met (221). Coverage is not available for drugs, such as laetrile, that are marketed without FDA approval (45 Fed. Reg. 110, June 5, 1980).

Charges associated with the administration of certain experimental cancer drugs, "group C" drugs, may be covered under Medicare although the drugs have not received final FDA marketing approval. Since the mid-1970s, group C drugs have been distributed by the Cancer Therapy Evaluation Program of NCI's Division of Cancer Treatment in cooperation with FDA to make promising drugs available outside of a clinical trial for some terminally ill patients. While the drugs themselves are given free of charge, there are costs, such as hospital or physician charges, associated with their administration (10,221,589). For a drug to be placed in group C, NCI must determine that the drug has shown, in at least two studies, "evidence of reproducible relative efficacy in a tumor type, which [will] alter the pattern of care of the disease' (964), or evidence indicating the drug has the potential to affect the standard of care (10). Distribution of group C drugs is limited to physicians registered as investigators with NCI, who are also required to report any adverse reactions (589).

Medicare clearly excludes coverage of treatments intended only to improve the general health of the patient, and not to treat a specific illness. For example, it is unlikely that charges for detoxification treatments, such as sweat baths or supervised fasting, given to remove toxins from a cancer patient, would be covered. However, charges for vitamin B 12 therapy for the treatment of pernicious anemia will typically be covered, since this is an accepted medical practice (877).

Medical services obtained outside the United States are not covered by Medicare, except in cases in which the foreign hospital was closer to or more accessible than the nearest adequately equipped U.S. hospital. In addition, the foreign hospital must meet HCFA's definition of 'hospital," and be accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) or meet local accreditation requirements equivalent to those of JCAHO (221) (42 CFR 405.153 and 42 CFR 405.313, October 1987 edition; 42 USCA 1395y(4)).

Coverage of services by physicians[14] who are not doctors of medicine (M.D.s) or osteopathy (D. O. S), or by other health care professionals,[15] is limited under Medicare. For example, coverage of chiropractic service is "specifically limited to treatment by means of manual manipulation. . . . The manual manipulation must be directed to the spine for the purpose of correcting subluxation demonstrated by x-ray to exist" (221).[16] Medical services rendered by all other types of health professional, with only a few exceptions, are covered by Medicine only if they are incident to a physician's professional services and only if there is direct personal supervision by the physician (221). Medicare does not reimburse for medical services given by several health professionals who are often associated with unconventional cancer treatments, including acupuncturists, homeopaths, naturopaths, and masseurs, even if such treatment was ordered by a physician. Nutrition services are reimbursed only to hospitalized patients (791).

Blue Cross/Blue Shield

There are 78 regional Blue Cross and Blue Shield (BC/BS) plans selling insurance within designated geographic areas and writing their own insurance contracts (56). Contract language affecting unconventional cancer treatments, therefore, may vary widely although some generalizations hold. Typically, M.D.s, D.O.s, podiatrists, chiropractors, dentists, and optometrists practicing within the scope of

[14] According to the Social Security Act, "physician" is defined as a doctor of medicine, doctor of osteopathy, doctor of dental surgery, doctor of dental medicine, doctor of podiatric medicine, doctor of optometry, or a chiropractor, who is legally authorized to practice his or her healing profession in the State in which he or she practices and who practices within the scope of that license (Compilation of the Social Security Laws 1981 section 1861(r)).

[15] Recent amendments t. Medicare now permit limited coverage for the services of selected health care professionals, including certified nurse anesthetists, certified nurse-midwives, and clinical psychologists (42 USCA supplement 1395(x) (bb)(ff)(gg)).

[16] Additionally, the chiropractor must be licensed or, in States without licensing, otherwise legally permitted to practice by the State (USCA supplement 42 1395x (r) 1988).

their licenses are accepted BC/BS providers (641). However, differences exist among plans due to ***variations in State laws and regional medical needs (641,815). Claims for medical services obtained in foreign countries are usually reviewed on an individual*** basis. Coverage may be available for such claims, as long as the plan determines the services were medically necessary (56,641).

BC/BS plans may also seek coverage recommendations from their trade association, the Blue Cross and Blue Shield Association (BCBSA). Two programs within BCBSA, the Medical Necessity Program (MNP) and the Technology Evaluation and Coverage (TEC) Program, evaluate the effectiveness, efficacy, and medical necessity of new or emerging (in the case of TEC) and well-established (in the case of MNP) procedures and devices. Except in a few cases, these programs are purely advisory, and their role is to issue coverage recommendations to member plans (56,447,851). A recent survey of plans showed that 36 percent "almost always" use TEC recommendations as issued, while another 62 percent occasionally alter TEC recommendations to better conform to local conditions. In this same survey, 58 percent of the plans indicated that "TEC Program publications [are] the single most important resource for new technologies" (343).

TEC will not recommend that a technology be covered unless it meets the following five criteria (87,88):

1. It must have obtained final approval from the appropriate government regulatory bodies (FDA approval to market for the specific indications and methods of use for which BCBSA is evaluating the technology).
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes (including well designed trials, the results of which are published in scientific peer-reviewed journals).
3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

Few unconventional cancer treatments meet these criteria, largely because of a lack of clinical evidence and lack of publications in scientific peer-reviewed journals. TEC has evaluated only one unconven-***tional cancer treatment so far, ozone treatment, which it labeled investigational (86). If FDA has not given a drug or biologic final marketing approval for the indication for which it was used, BCBSA usually recommends against reimbursement. Few drugs or biologics used in unconventional cancer treatments would meet this criterion. In the past, BCBSA has chosen not to evaluate or issue coverage recommendations for drugs and biologics that do not have FDA final marketing approval or are not used for the indication(s) approved by FDA. BCBSA is, however, in the process of reevaluating their role in assessing drug coverage (56,343).***

For examples of the process by which coverage policies may be determined, OTA contacted the medical directors of two large BC/BS plans. At BC/BS of New Jersey (BCBSNJ), members of the medical advisory staff determine if a medical service may be covered. They typically consult: 1) the published scientific literature, recognized experts in the field, professional organizations, reports or position papers from various technology assessment programs, including the National Center for Health Services Research and the Clinical Efficacy Assessment Program of the American College of Physicians; and 2) the recommendations of the Medical Advisory Panel of BCBSA. Additionally, in 1981 BCBSNJ createda"Multispecialty Advisory Committee," (MAC) which comprises local physicians who represent approximately 28 different disciplines. On average, this committee meets four times annually and acts in an advisory capacity. MAC may review the coverage recommendations of BCBSNJ as well as suggest new coverage policies. BCBSNJ uses criteria quite similar to those of the TEC program (described above) when determining the coverage status of a medical service (241).

BS of California uses a slightly different format, convening a' 'Medical Policy Committee" that sets coverage policies. The Medical Policy Committee, which is composed of both physician and nonphysician members of BS of California's Board of Directors, meets four to five times a year in an open session to review specific technologies. BS staff conduct literature searches and write an analysis of the state of each technology, and get written opinions from specialty societies and national organizations before meetings. In addition, BS invites oral testimony from outside experts, including health economists and members of specialty societies, to augment the written analyses. BS of Califor-

nia *follows the five TEC criteria (listed above) to determine if a technology is investigational or established (780).*

Commercial Plans

Most commercial health insurance policies cover treatments considered part of "standard medical practice," but do not offer coverage for treatments considered to be "experimental' or not 'medically necessary. ''17 Some insurers may specify the criteria necessary for a treatment to fit these terms. For example, some policies reviewed by OTA indicated that to qualify for coverage, treatments would need approval from FDA (220,659), or "the cognizant college or academy of medicine as identified by the American Medical Association" (659). Other policies do not specify criteria, although many indicate that claims will be adjudicated based on generally accepted standards of U.S. medical practice.

Many of the policies that OTA reviewed exclude the following from coverage: nonprescription drugs, nutritional supplements or vitamins (even if they are prescribed), chiropractic services (except as specified in the contract), services given by a health professional who does not meet the insurer's definition of doctor, and services given in an institution that does not meet the insurer's definition of hospital. A few policies specifically exclude colonic therapy (227); serums, preparations, and remedies (including homeopathic) that by law do not require a prescription (226,227); and chelation therapy, except in the treatment of lead, mercury, gold, or arsenic poisoning (28 1,655). Additionally, some policies contain clauses restricting coverage to those cancer treatments that are considered by most knowledgeable physicians to have a success rate of at least 50 percent survival 5 years following treatment (628).

A few policies explicitly state that medical services obtained outside the United States are not covered, except in an emergency. These policies generally do not cover even emergency medical treatments received after a designated period of time (usually 30 to 90 days) from the date of leaving the United States (225,226,227).

Some policies stipulate which licensed or certified practitioners' services are covered. In the policies reviewed by OTA, covered practitioners included M.D.s, D.O.s, podiatrists, chiropractors, dentists, optometrists, clinical psychologists, clinical social workers, psychiatric social workers, midwives, and, occasionally, registered nurse anesthetists. For selected medical treatments, a few policies extend coverage to naturopaths, homeopaths, biofeedback technicians, nutritionists/dietitians, and massage therapists (227). Other policies use more general language when defining which practitioners' services are covered; for example, "A 'doctor' is a licensed practitioner of the healing arts acting within the scope of the license" (657).

Coverage for investigational or experimental treatments may be easier to obtain under health insurance policies with case management' clauses; such policies are available to consumers at additional cost (357). Under 'case management' provisions, treatments are evaluated on an individual basis, taking into consideration the health of the patient and the possible alternatives to the selected treatment. Coverage may be possible for a treatment the insurer considers investigational, if it is the best alternative available to the particular patient. However, the insurer first would have to agree that an unconventional cancer treatment complied with its definition of "investigational" or "experimental" before reimbursement could be received. An exception may also be made for a patient who is a member of a group policy if the group agrees to pay higher premiums for the coverage of one member's unconventional cancer treatment (320). The frequency with which this mechanism is used is not known.

Claims Evaluation

At the time a claim for reimbursement is submitted, the insurer determines whether the medical services qualify for coverage under the terms of the insurance contract. Recently, third-party payers have begun interpreting contract language more narrowly as well as relying more heavily on the safety and efficacy evaluations of Federal agencies, mainly FDA (599). They are also attempting to reduce the number of fraudulent insurance claims

[17]To accurately describe the thousands of health insurance policies available in the United States would be impossible; significant variations exist not only between insurers but also among policies of a single company. This section should only be regarded as a descriptive review of several current health insurance policies.

they pay, including those for unconventional cancer treatments.

Claims for unconventional cancer treatments are usually filed either directly by patients, or on their behalf by an insurance billing consultant, who may be an agent of an insurance company, or may be affiliated with a clinic. The consultant's job is to understand the details of the contract and to obtain as much reimbursement for the patient as is legally possible (228). Patients who use unconventional cancer treatments locate billing consultants through other patients, treatment clinics, and attorneys who practice medical claims collection (951). Insurance billing consultants may be able to obtain reimbursement for an unconventional cancer treatment by providing information in the claim form that will explain why the medical services should be covered under the provisions of the insurance contract. Even if coverage is denied for the treatment itself, reimbursement for ancillary services, such as diagnostic tests, hospital room and board, or physician visits, may be provided (951).

The Process of Evaluation

Evaluating a claim for an unconventional cancer treatment may be difficult for an insurer since the treatment may be unknown, or it may involve a standard treatment used in an unconventional manner (such as low-dose chemotherapy). Claims for unconventional cancer treatments are often passed up the echelons of claims reviewers until a reviewer is found who is familiar with the treatment, or, eventually, to the office of the medical director where an individual assessment of the treatment is made. If, however, a precedent or policy exists for a particular unconventional cancer treatment, the claim may be resolved at a lower level (241,780,908). All third-party payers set their own reimbursement and evaluation policies, and more or less information may be required by any one carrier to evaluate the claim.

Medicare Evaluation Process and Criteria

HCFA relies on outside regional contractors (BC/BS plans, commercial carriers, and professional review organizations) to process Medicare claims. Although all contractors use Medicare coverage guidelines when evaluating a claim, the contractors may vary in their interpretation of the guidelines (814,870). The absence of a clear national policy concerning what is considered "reasonable and necessary" treatment, the myriad rules and regulations of the Medicare program, the high degree of independence in judgment given to contractors to adjudicate claims, and the decentralized process that controls the development of coverage guidelines all contribute to the varying interpretations of guidelines (447,814,870). The HCFA national office does make a certain number of national coverage decisions each year that are communicated to the contractors. In addition, contractors may consult a number of sources when adjudicating coverage, including HCFA's information manuals, physician consultants, and regional offices; the contractor's own medical staff; peer-reviewed scientific literature; local specialty societies; university medical centers; a national insurance association; or colleagues from another third-party payer (447,870).

While HCFA clearly prohibits coverage for some unconventional cancer treatments, such as colonic irrigation, cellular therapy, and laetrile (221), policies for other unconventional cancer treatments are not stated explicitly.

BC/BS Plans

The Medical directors of BC/BS plans[18] assess questionable cases in light of current trends and accepted practices of the U.S. medical community. The director may consult Federal agencies, peer-reviewed scientific literature, specialty groups, individual and local physician consultants, or members of an advisory panel made up of local physicians, for advice (56,241,780). In some cases, a medical director may ask the treating physician to explain the rationale for using a particular treatment (641).

Commercial Carriers

Medical directors of commercial carriers assess questionable claims in light of current trends and accepted practices of the U.S. medical community, and consult many of the same information sources used by HCFA and BC/BS. A 1987 survey of a subset of commercial insurers described the sources of information these companies most frequently use

[18] As mentioned earlier, the individual BC/BS plans set their own coverage and reimbursement policies.

when evaluating claims for cancer chemotherapy drugs.[19] All the companies surveyed used FDA, a local physician consultant, NCI, and AMA in their process of adjudicating claims. Nearly all the respondents consulted the ACS Unproven Methods Committee, 39 percent referred to a national physician consultant, 28 percent requested information from a university cancer center, and 28 percent consulted the Association of Community Cancer Centers. Several also indicated that they independently reviewed the medical literature (577).

Commercial carriers are becoming more attentive to claims evaluation, and are requesting evidence of safety and efficacy before reimbursement is approved. For some, a drug is not considered safe and effective unless it has been approved by FDA. In the 1987 survey of insurers mentioned above, half the respondents mentioned that FDA approval of a drug, device, or biologic was necessary for reimbursement; however, a significant percentage of companies also used more subjective criteria such as medical necessity (44 percent), safety and efficacy (28 percent), and acceptance by the medical community (28 percent) (577).

Appealing Reimbursement Decisions

Patients who are denied reimbursement but feel they deserve coverage under the terms of their contract may pursue several avenues of recourse. First, an appeal maybe made directly to the insurer. All insurance contracts indicate how an appeal may be fried, as well as the time period in which the insurer must respond to the claim. If the patient is unsatisfied with the outcome of the appeal, often another appeal may be submitted, or the patient may appeal directly to the medical director. A patient who remains unhappy with the reimbursement decision may write a letter of complaint to the State Insurance Commissioner. Because each State sets its own insurance laws, the State Insurance Commissioner is responsible for making certain that companies practicing in the State operate according to law (357).

Complaints submitted to an insurance commissioner are reviewed to ensure that the company has acted in accordance with the State insurance laws. As part of this process, the State Insurance Department may request a detailed report of the insurance company's finding and compare this information to the patient's insurance contract. An insurance commission may only determine if an insurer has violated any of the State insurance laws; insurance commissions typically do not have the authority to interpret the insurance contract, including phrases such as "medically necessary." If the insurance department determines the company violated the terms of the insurance contractor State law, it will request that the company pay the benefit. Depending upon State law, this request may or may not have the force of law. If the insurance commission believes the insurer has acted improperly, but did not in fact violate any State laws, the commission may recommend that the patient litigate (567,601,788). Since many disputed claims for unconventional cancer treatments center on the interpretation of the contract, especially phrases such as "medically necessary," a State insurance commission finding may have minimal effect on claims for unconventional cancer treatments.

Legal Challenges

As a last resort, patients who have been denied reimbursement for an unconventional cancer treatment have sued their insurers. Though the outcomes of these cases have varied, to a great extent patients have been successful in their suits. Two factors have contributed significantly to the success of patients in cases gaining reimbursement for unconventional cancer treatments. First, it is a basic tenet of contract and insurance law that a contract be viewed in the way most favorable to the insured.[20] The other contributing factor that has, in some cases, helped the insureds is the tendency of insurance companies to use language such as "usual and customary" or "reasonable and necessary," to describe covered services, making the contracts vulnerable to broad interpretation.

[19]Surveys were sent to the top 25 for-profit health insurance companies; 18 (72 percent) responded. Since no survey has been conducted on this topic with respect to unconventional cancer treatments, it is not possible to say whether the same information sources are used and whether they are used as frequently.

[20]Insurance contracts are usually considered adhesion contracts, the distinctive feature of which is that the weaker party (the insured) has no realistic choice as to the terms; they are given a take-it-or-leave-it option they cannot negotiate. In considering a dispute involving an adhesion contract, the law requires that the weaker party be given the benefit of the doubt, meaning any ambiguity in the contract is construed in the weaker party's favor (458). As noted by the judge in one such case, the court "must consider all the evidence in the light and with all reasonable inferences most favorable to the plaintiff" (687).

Disputes over the interpretation of unclear or ambiguous contract language have formed the basis of several lawsuits between third-party payers and patients who have used unconventional cancer treatments. The criterion used by courts for deciding whether a treatment should be covered is based on the *City of Carter Lake v. Aetna* decision in 1979: the court asks, What would a lay person believe is covered after reading the insurance policy? The answer to that question is then the criterion used by the court in its decision (194). However, the advantage that patients have in these cases is not insurmountable, as the outcomes of *R.A. v. Prudential* and *Free v. Travelers* show. In these cases, the policyholders claimed they expected reimbursement for laetrile and nutritional therapies because these treatments were 'reasonable and necessary' for the treatment of their cancer. However, the judges in these cases did not find this argument convincing, because it was demonstrated that the patients knew prior to treatment that neither laetrile nor nutritional treatments were considered to be effective by the American oncologic, medical, or regulatory communities. In both of these cases, the patients had signed informed consent documents or affidavits (to obtain laetrile) stating that the treatments were not FDA-approved or were not considered effective by the majority of physicians (37,304,734).

Other grounds for suit concern the medical standards by which therapies are judged to be reasonable and necessary. Plaintiffs often cite their interpretation of this clause when asserting that they reasonably expected reimbursement. In *Henne v. Mutual of Omaha, the* insured's policy in part excluded "services and supplies not prescribed by a doctor in accordance with generally accepted professional medical standards. The plaintiffs argued that nutritional and vitamin treatments conformed to "generally accepted professiona.l medical standards," because a significant minority of U.S. physicians used such therapy, and because the Commonwealth of Virginia had not disciplined the physician for improperly practicing medicine. The court ruled against the plaintiffs, however, finding that the treatment did not fit "generally accepted professional medical standards,' in part because it was not accepted by "a majority of practicing physicians' (394).

In *McLaughlin v. Connecticut General the* judge held that the insurance company should not have used FDA approval as the medical standard by which coverage was approved or denied, since this requirement was not specified in the contract (600). In this case a cancer patient's claims for reimbursement for Immuno-Augmentative Therapy (IAT) had been denied by Connecticut General for the sole reason that the treatment was not FDA-approved.

Similarly, in *Shumake v. Travelers the court ruled* that the insurer had to reimburse for laetrile and vitamins, because they were determined to be medically necessary in accordance with the terms of the insurance policy. The plaintiff's policy permitted reimbursement for a treatment if the "duly qualified attending physician" determined such treatment was medically necessary. The company argued that the court should consider "general standards of medical or scientific acceptance' in its ruling. The court rejected this argument, finding that if the insurer intended to use "general standards of medical or scientific acceptance' in deciding whether to reimburse, it should have clearly defined such standards (801).

Plaintiffs have also argued that improvement in their physical condition should be the medical standard used to determine coverage. In *Zuckerberg v. Blue Cross and Blue Shield,* one of the three issues the court looked at in order to determine whether the plaintiff should receive reimbursement was the subjective benefit of the Gerson therapy. The court posed this question to the insurer: "[effectiveness is measured by its results. How could defendant exclude this treatment as ineffective without ever looking at the results?' The fact that the third-party payer did not consider the subjective benefit to the patient contributed to the court's ruling in favor of the plaintiff (992). However, upon appeal both the State appellate and supreme courts overturned the ruling on other grounds (related to the other two original issues) (993). Similarly, in *Dallis v. Aetna the court,* after refusing the insurer's motion for an immediate judgment, allowed testimony from IAT patients who testified that the treatment in question had benefited them (247).

The argument of subjective benefit, however, does not ensure coverage. In *Dallis v. Aetna,* the appeals court judge allowed the testimony because it "was relevant to the determination of a fact in issue, namely, whether the IRC treatment was a 'necessary' treatment for cancer,' and because the witness' opinions "were rationally based on their own perceptions.' But, he noted that "[t]o the

extent that the witnesses' opinions lacked a scientific basis, appellant had the opportunity to expose this fact" (247), which presumably would have undermined the effect of their testimony to some extent. In another case, Free v. Travelers, testimony of subjective benefit was rejected by the judge because, "[a]s one court noted, it is simply not enough to show that some people, even experts, have a belief in [the] safety and effectiveness [of a particular drug]. A reasonable number of Americans will sincerely attest to the worth of almost any product or even idea" (629).

There are also several cases in which courts have confirmed the insurer's right to limit medical benefit coverage. In Wehmeyer v. Prudential, the judge upheld a patient's right to free choice of treatments, but also affirmed the insurer's "right, in the course of reasonable judgment, to confine its coverage to those treatments proven to be effective and medically productive" (944). The court in Risner v. Blue CrosslBlue Shield of Michigan ruled that insureds could not expect to "obtain any treatment whatsoever he chooses at any facility he chooses and afterwards collect from his health insurance carrier' (759).

Other judges have ruled in favor of insurers by upholding their responsibility to promote public good. In R.A. v. Prudential, the judge did not permit a liberal interpretation of the term "necessary," because that could result in payment for many ineffective or less effective therapies. Increases in benefits paid to insureds would create higher premiums for all; "[t]hose who accepted the logical limit of effective treatments would, as a condition for coverage of same, be forced to pay for worthless treatments as well . . . there is no public good in this" (734).

The success of patients in getting the courts to find in their favor seems to have prompted responses from both insurance companies, who are more precise in their contract language, and their lawyers, who have developed at least one new strategy for defending suits that do arise. More and more, insurance companies have had cases removed from State courts to Federal courts, arguing that the jurisdiction of a Federal law, the Employee Retirement Income Security Act (ERISA), which covers group medical plans, preempts the State laws that would otherwise apply. The standards of evidence required by ERISA are different from those required in contract law. ERISA gives the administrator of a group health plan discretionary authority to decide claims. Further, ERISA requires that denial of coverage "must be upheld unless it was arbitrary, capricious, made in bad faith, not supported by substantial evidence or erroneous as a matter of law" (462). These are standards of evidence that are more favorable to the insurer than those required under contract law. Because this strategy is just evolving, particularly in the context of unconventional cancer treatments, it is not clear how successful it will be. However, in one of the earliest pertinent ERISA cases, McLaughlin v. Connecticut General, the more stringent standards did not help the defendant. In this case, the two major claims by the plaintiffs were breach of insurance contract and breach of implied covenant of good faith and fair dealing. The insurance company argued, among other things, that ERISA preempts the State insurance and contract laws. The judge found, however, that although ERISA covered the insurance plan involved, it "did not preempt State law claims for breach of contract and implied duties of good faith and fair dealings' (600). The court found in favor of the plaintiff. In other ERISA cases (e.g., Filary v. General American Life Ins. Co., 711 F.Supp. 258 (D.Ariz., 1989)) involving unconventional treatments, but not for cancer, decisions have favored the insurance companies.

The above examples represent a few of the legal issues raised during court trials. According to one advocate of unconventional treatments, by threatening to sue, many patients can obtain payment for the treatment through an out-of-court settlement (951). However, if an insurer will not settle out of court, patients must be prepared to pay attorneys' fees, wait until the trial can be heard by a jury or judge, and endure a possibly long trial. In one case recently decided in favor of the patient, the trial lasted only 3 days, but attorneys' fees for the patient were $97,361, and the patient's out-of-pocket expenses were approximately $24,000.[21]

[21] In this case, the judge ruled that cancer treatment given by Stanislaw Burzynski to a woman with a malignant brain tumor was "usual and customary" under the terms of the insurance contract. Among other provisions, the patient was awarded payment of all past medical bills, which totaled approximately $200,000 (192).

Fraudulent Insurance Claims

Fraudulent insurance claims of various types are submitted for all kinds of medical services (412,769), including unconventional cancer treatments.[22] U.S. third-party payers allege that several unconventional cancer clinics and at least one billing service company have committed what falls into the category of insurance fraud, but the prevalence of fraudulent claims is unknown. Many fraudulent claims submitted for unconventional cancer treatments request reimbursement for "chemotherapy.' A minority of unconventional health care providers treat patients with chemotherapeutic regimens that are recognized by the medical community (321). Unconventional cancer treatment claims have also been submitted for chemotherapy or "non-toxic chemotherapy' followed by a set of initials; for example, "chemotherapy AMGL" has been used to represent laetrile treatments. Third-party payers disagree about whether such claims deliberately misrepresent the services rendered, thus constituting fraud, or simply reflect the clinic's definition of their treatment. In this and all other possible identifications of fraud, the pattern of claims submissions ultimately determines if an individual is deliberately and knowingly committing fraud (250,320,856,908).

More sophisticated insurance fraud often involves billing service consultants familiar with numerical coding systems used by providers and insurers in the United States. Two of the coding systems used are the International Classification of Diseases (ICD-9th revision) and the Current Procedural Terminology (CPT-4th edition). The ICD codes represent various diagnoses and CPT codes denote the treatment administered to the patient. If the CPT code is an appropriate match for the ICD code, the insurer will generally approve coverage without further investigation. Billing companies that allegedly commit fraud give the unconventional treatments CPT codes that not only match the ICD code for the patient, but also represent accepted medical treatments. For example, treatments that are not covered under the terms of the policy, such as coffee enemas or laetrile, might be coded as a type of chemotherapy, which would be covered under the contract (228,321). Claims submitted in this manner appear on paper to be valid, and some insurers believe many fraudulent claims of this type go undetected by their claims departments (228,320,321).

Third-party payers have increased their efforts to reduce the number of fraudulent claims that are reimbursed. More commercial carriers have established fraud divisions, both at company headquarters and at regional and local offices (228,250,269,856). In addition, several private insurers, BC/BS plans, and State and Federal agencies have joined the National Health Care Anti-Fraud Association (NHCAA), a group whose stated mission is to improve prevention, detection, and prosecution of health care fraud (269). The recent application of an old law, the Racketeer Influenced and Corrupt Organizations Act (RICO), to insurance fraud may represent a new mechanism for insurers to prosecute fraudulent providers. An insurer only needs to show it was hurt by the practitioner's " 'pattern of racketeering activity' (allegations of several counts of mail or wire fraud will suffice) in furtherance of an enterprise (such as a professional corporation) that affects interstate commerce (the insurance business)' (412). The drawback of RICO cases is that they require a large allocation of resources to prove the charges because the plaintiff must show the elements of fraud (927). One case involving a RICO action is currently pending against an unconventional practitioner. The suit is a counterclaim in the legal battle between Stanislaw Burzynski and Aetna.

It is important to note that many patients and practitioners do not believe they are committing an illegal act if they misrepresent on an insurance claim form the treatment they received. These individuals believe their claim would otherwise be rejected outright, without being reviewed by medical professionals who the patient and practitioner believe are most capable of evaluating the effectiveness of the treatment.

SUMMARY

Medicare, BC/BS plans, and most commercial third-party payers typically do not cover unconventional cancer treatments, though at least some unconventional cancer clinics imply that they do. Coverage is limited by clauses requiring covered medical services to be recognized as medically necessary by the U.S. medical community; limiting

[22] Note that in this chapter, "insurance fraud" is defined as an intentional misrepresentation of the facts in order to obtain reimbursement. This is distinguished from "health fraud," in that it does not necessarily involve false or unsupported claims of a treatment's effectiveness.

coverage of drugs and biologics to those approved by FDA or included in drug formularies; and (especially for Medicare) restricting coverage of medical services to specified health care professionals.

Third-party payers may permit coverage of patient care expenses associated with clinical trials or the Group C drugs. Although these drugs or biologics remain investigational until given FDA final marketing approval, most third-party payers do not consider these drugs comparable to unconventional cancer treatments. For most third-party payers, a crucial distinguishing feature of investigative drugs is that clinical data exist that suggest some degree of efficacy. Furthermore, the drug is identified and described, as is the scientific method used to produce the clinical results. At the same time, coverage for investigational drugs or for drugs that are used for other than FDA-approved indications is becoming more difficult to obtain.

Some claims for unconventional cancer treatments may be reimbursed unwittingly, but third-party payers are focusing their efforts on halting such reimbursements. Patients who choose to pursue their claims may be able to obtain some reimbursement, especially through an out-of-court settlement, though the outcomes of court cases have been mixed. Unless insurers undergo a major shift in their reimbursement policies, it is unlikely that it will become easier to obtain coverage for these treatments, as the general trend among insurers is to be tougher about reimbursement criteria for all types of medical services.