Analysis of health insurance cover for reproductive immunology

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The objective of this study was to document the current state of health insurance cover for reproductive immunology in the USA. A survey of couples who had given birth to a child within the last 2 years while they were being treated with lymphocyte immunotherapy at the Reproductive Medicine Clinic of the Finch University of Health Sciences/The Chicago Medical School (FUHS/CMS), North Chicago, IL, USA, produced 61 completed questionnaires from couples in 16 states, representing a response rate of 55%. The Reproductive Medicine Clinic at the FUHS/CMS is a major centre that treats couples with reproductive immunological problems. These couples had experienced repeated pregnancy losses that were diagnosed as immunological in nature. This prospective study documents the insurance reimbursement of couples receiving lymphocyte immunotherapy who subsequently became parents. The findings indicate that 80% of couples had insurance claims initially denied for reproductive immunotherapy-related services. The most common reason given for a denied claim was that the treatment was experimental. Couples took further action and almost all received cover. Cover for immunotherapy-related services averaged 65% of the cost. The percentage of expenses covered by the insurance was quite variable. The survey indicates that insurance cover is provided if patients are willing to take action.

Key words: health insurance/immunotherapy/reproductive immunology/USA

Introduction

With the high cost of health care, everyone is naturally concerned about which insurance companies are willing to pay for services. Most people do not know what their insurance company will pay for a particular problem, if in fact they will pay anything at all. The expectation is that insurance companies cover the expenses related to certain types of health care. Insurance companies generally define a covered expense as a reasonable expense incurred by a covered person for any of the services or supplies which are medically necessary for the treatment of a disability (Davids, 1990). ‘Necessary’ normally means consistent with currently accepted medical practice and generally considered by physicians to be appropriate for a given medical condition. Insurance companies reserve the right to determine reasonable and customary charges for medical treatment, and this is the amount on which they base their payment. This reasonable and customary amount declared by an insurance company may be far less than the amount charged to the patient.

In addition, insurance companies typically will not deem a medical service, supply, treatment or expense as being necessary if it is experimental in nature. They generally consider a service to be experimental if it meets at least one of these conditions: (i) it is within the research or experimental stage; (ii) it involves the use of a drug or substance that has not been approved by the US Food and Drug Administration, by issuance of a New Drug Application or other formal approval; (iii) it is not in general use by qualified physicians; or (iv) it is not of demonstrated value for the diagnosis or treatment of sickness or injury. An insurance company may determine that a treatment is experimental and therefore not to be a covered expense, and thus leave the burden on the patient to convince them otherwise. Not all people have the resources to perform this very time-consuming process.

Thus in many cases the amount of compensation one gets is determined by how much the insurance company is willing to pay. Many cases are not very clear cut and the amount reimbursed is a function of the policy holder’s ability to battle with the insurance company. Today, much emphasis is being placed on health care reform and on comparing health care and covered expenses in the US with that in other countries (Glaser, 1991). This is an important topic for everyone, raising much concern about what would be considered a necessary treatment and what would be the corresponding level of reimbursement for the service.

Health insurance companies are in the business of managing risk (Dorfman, 1991). They understand the elements of uncertainty and risk, and have sophisticated techniques available to manage risk to remain profitable (Engemann et al., 1994). They are also obliged to reimburse their policy holders for necessary medical treatment. Here we will focus on the current practices of insurance companies in the US related to cover for reproductive immunology.

Materials and methods

Medical background

Of the couples of child-bearing age, 15% will encounter some form of infertility, where infertility is defined as not being able to produce
a viable pregnancy within a 1 year trial (Pratt et al., 1985). Much is being done medically to aid these couples, and advances in technology and medical science continue to offer increasing hope to them. Some couples are able to achieve pregnancy but unfortunately their pregnancies continue to end in miscarriage. Most couples with unexplained recurrent miscarriages will not become parents unless they are screened for an array of immunological complications (Speroff et al., 1989). Repeated pregnancy loss affects one in 300 couples attempting to start a family (Roman, 1984). In >60% of these couples, the cause is not apparent after ruling out hormonal, structural, infectious and chromosomal problems (Coulam, 1991).

Couples with repeated pregnancy loss have been studied to determine the maternal immune response necessary to protect the fetus (Beer et al., 1981). Therapy for women lacking the proper response is paternal lymphocyte immunotherapy, with success rates of women becoming mothers of >80% (Kwak et al., 1992). In addition to this primary problem, repeated pregnancy loss is associated with the increasing appearance in the mother of autoantibodies to phospholipids essential for placental development. Although these women do not have clinical autoimmune disease, subsequent pregnancies miscarry because of this autoimmune condition. Immunological testing is available. Immunological assessment of the couples can document the presence of this type of immune problem. Prospective studies have confirmed that most women can be successfully treated for their malady prior to another pregnancy. Women who have autoantibodies to phospholipids and DNA require treatment with low doses of aspirin and heparin from the onset of the cycle of conception, and in some cases prednisone. With this therapy, 74% become mothers.

Survey method
There are several medical centres in the US that currently treat couples with this immunological problem. A major treatment centre is the Reproductive Medicine Clinic at the Finch University of Health Sciences/The Chicago Medical School (FUHS/CMS), North Chicago, IL, USA.

To assess the insurance cover for reproductive immunology in the US, the authors surveyed couples who had had a child within the last 2 years while they were being treated at FUHS/CMS. These couples experienced repeated pregnancy losses that were diagnosed as immunological in nature. A total of 120 couples were eligible; nine did not have forwarding addresses, and therefore 111 questionnaires were sent out. We received 61 completed questionnaires from couples in 16 states. We did not wish to upset unsuccessful couples by querying them about insurance matters, therefore they were not included. We will summarize the results of the survey here.

Results

Insurance plans
All of the 61 couples had a primary health insurance carrier, while 25 (41%) additionally had secondary cover with another company. Secondary carriers generally pay the co-insurance amount (0–20%) of the reasonable and customary fee not paid by the primary carrier, as determined by the primary carrier.

There were 34 different insurance carriers reported on in this study, several of whom appeared in multiple responses. We have analysed the variability of cover provided by the same companies below.

The insurance plans were predominantly employer sponsored (87%). Some couples obtained insurance through professional groups (9%), and relatively few purchased individual policies on their own (4%).

| Table I. Reasons given by the insurance company for denying 49 claims |
|-----------------|-----------------|
| Reason                              | Number |
| Treatment is experimental          | 37     |
| Infertility treatments are not covered | 16     |
| Treatment is not necessary          | 11     |
| Pre-existing condition              | 2      |
| Physician not part of the provider network | 2      |

| Table II. Follow-up activities on 49 claims after being denied cover by the insurance carrier |
|-------------------------------------------------|-----|
| Follow-up activities                           | Number |
| Resubmitted claim                              | 42   |
| Provided letter from physician                 | 40   |
| Called insurance company                        | 39   |
| Wrote to insurance company                     | 31   |
| Appealed to employer                           | 12   |
| Sued insurance company                          | 2    |
| Sent literature to the insurance company        | 2    |

Most of the insurance plans that the couples subscribed to were fee-for-service (58%), i.e. major medical, indemnity plans or extended benefits. Some couples had plans through a Preferred Provider Organization (PPO; 33%), while relatively few had plans through Health Maintenance Organizations (HMO; 9%).

Insurance cover
Several hundred physicians from all parts of the USA and abroad refer their patients to the Reproductive Medicine Clinic at FUHS/CMS. The criteria for acceptance for treatment are three or more miscarriages with no other cause found, i.e. genetic, infectious, hormonal or anatomical, and a lack of alloimmune recognition and/or autoimmune serological abnormalities. All 61 couples in the survey fitted the criteria, received treatment at FUHS/CMS and subsequently delivered healthy babies. They submitted claims to their insurance carriers for services performed at FUHS/CMS.

Only 12 of the 61 couples (20%) did not have claims denied initially. Those couples whose claims were not initially denied received an average of 78% insurance cover of the total cost of services performed at the Reproductive Medicine Clinic, FUHS/CMS. Of the remaining couples, 49 of the 61 (80%) had their claims denied initially by their insurance companies. The insurance companies gave at least one reason for each denied claim, as presented in Table I. Insurance cover denial varied by the type of insurance. Specifically, fee-for-service insurers initially denied 84% of claims, PPO initially denied 67% of claims and HMO initially denied all of the claims.

All 49 couples whose claims were initially denied took further action to receive cover from their insurance companies. The follow-up activities are displayed in Table II.

The median number of follow-up activities by the couples was four, and two couples used all the actions in Table II. The insurance companies took at least 1 month and up to 1 year.
to review the cases. The average appeal took slightly more than 4 months. Figure 1 shows the distribution of time to settle a denied claim. This group of 49 couples whose claims were initially denied received an average of 61% insurance cover of the total cost of services performed at the Reproductive Medicine Clinic, FUHS/CMS. This was significantly different from the 78% cover received by the 12 couples whose claims were not initially denied (P = 0.03). Figure 2 displays the distributions of insurance cover for both the couples whose claims were initially denied and the couples whose claims were initially accepted.

The final percentage of the total cost of services covered by the insurance for the 61 couples depended on the type of insurance cover. The percentage cover of the total cost of services by the type of insurance was 69% for fee-for-service, 57% for PPO and 40% for HMO. The type of insurance does make a significant difference (P = 0.038).

The cost incurred comprises three types of service: patient consultation, immunotherapy and laboratory tests. The average percentage of the cost of service covered by the insurance for the 61 couples was 59% for consultation, 55% for immunotherapy and 67% for laboratory tests. Reimbursement for laboratory tests significantly differed from the other two services (P < 0.05).

### Comparing reproductive medical cover

Couples referred for testing and treatment for immunologically based miscarriages had already received medical services elsewhere for other possible infertility/miscarriage factors. These services included genetic studies, antibiotic therapy, surgery and Pergonal/Metrodin/in-vitro fertilization cycles. Table III compares the percentage cover of the total cost of these services with immunotherapy-related services.

The insurance cover of immunological and infertility services was related, although at significantly different levels. The average percentage of the cost of services covered by the insurance for infertility services which were not immunotherapy related was 77%. Reimbursement for immunotherapy-related services averaged 65%, which differed significantly from the infertility services using paired samples (n = 44; P = 0.001). The Kolmogorov-Smirnov goodness-of-fit test showed that the distributions of insurance cover for immunology- and infertility-related services were not equivalent (P < 0.01). The insurance cover for immunotherapy- and infertility-related services was very highly correlated. The coefficient of determination between these two types of medical service was 0.79 (P < 0.00005).

Having two insurance plans did not improve cover significantly because of the coordination of benefits. There was no significant difference between the average percentage of cost covered for immunology services for the couples who had only primary insurance (67% cover) compared with those couples who had primary and secondary cover (62%). Likewise, there was no significant difference between the average percentage of cost covered for infertility services for the couples who had only primary insurance (75%) compared with those couples who had primary and secondary cover (78%).

The amount of insurance cover for immunological services over the 2 year period of the survey did not change. A regression analysis of the percentage of cost covered by the insurance as a function of the time of the couple's first visit to FUHS/CMS revealed no significant relationship (t = 0.139).

### Dispersion in the level of cover

The dispersion of cover was quite large. The SD of the percentage of cost for immunological services reimbursed by the insurance was 29% (n = 61). Nine insurance companies insured multiple couples responding to the survey, comprising 36 cases. Insurers with multiple claims showed less variability (SD 22%) than the group which had single claims, albeit not significantly different. The mean cover for both groups was the same.

<table>
<thead>
<tr>
<th>Service</th>
<th>Percentage paid (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic studies</td>
<td>88</td>
</tr>
<tr>
<td>Surgery</td>
<td>88</td>
</tr>
<tr>
<td>Antibiotic therapy</td>
<td>76</td>
</tr>
<tr>
<td>Pergonal/Metrodin/in-vitro fertilization cycles</td>
<td>70</td>
</tr>
<tr>
<td>Immunotherapy-related services</td>
<td>65</td>
</tr>
</tbody>
</table>

Table III. Percentage of cost of each service finally covered by insurance
Insurance legislation

Several states have provided legislation to mandate insurance cover for the medically necessary treatment for infertility, i.e., an 'infertility or family building mandate'. This legislation amends the insurance law to prohibit policies which provide hospital, surgical or medical cover from denying cover for the diagnosis and treatment of correctable medical conditions, otherwise covered by the policy, solely because they result in infertility. This law is designed to ensure that cover is not arbitrarily denied.

At the time of their miscarriage treatments, four couples (7%) knew that their state had infertility or family building mandate legislation, 12 couples (20%) knew that their state did not have a family building mandate, and the other 45 couples (74%) did not know. In all, 92% of the couples in the survey considered the lack of miscarriage/infertility cover as a discriminatory practice on the part of the insurance companies.

Support in filing claims

Couples who are denied insurance cover found little assistance except from their physician. In all, 82% of the couples who were initially denied insurance cover for reproductive immunology services were assisted in obtaining cover by having their physician provide a letter to the insurance company explaining the need for medical treatment. Unfortunately, 69% of the couples indicated that the level of help received from their employers’ benefits officers was less than satisfactory. Likewise, 62% of the couples indicated that their insurance claims specialists also provided a less than satisfactory level of assistance.

Discussion

Miscarriage, a disappointing and distressing experience for anyone, is especially devastating for the one in 300 couples who experience three or more consecutive miscarriages. Half of such couples are told that no cause can be found for the miscarriages, and they are typically advised to keep trying even though their chance of producing a live baby diminishes greatly with each miscarriage (Cowchock and Smith, 1992). Now, thanks to a better understanding of immunological factors that protect or destroy the developing placenta and fetus, simple new therapies are yielding high rates of successful pregnancies among the thousands of women who have experienced previously unexplained recurrent miscarriages.

Because there are only a handful of centres that provide reproductive immunological treatment, and FUHS/CMS is a major one, this study represents the state of insurance for reproductive immunology in the USA.

Primary findings

In all, 80% of the couples had their insurance claims initially denied for reproductive immunotherapy-related services. The most common reason given for a denied claim was that treatment was experimental. The couples took further action, and almost all received cover. Cover for immunotherapy-related services averaged 65% of cost. The percentage of expenses covered by the insurance was quite variable.

To deny claims, insurance companies used the assertion that reproductive immunotherapy was experimental and unnecessary. Depending upon the insurance company, various levels of effort on the part of the filing couples were required to obtain cover.

The cost of reproductive immunotherapy is usually several thousand dollars per pregnancy and may climb to >10 000 dollars. There are also added costs of travel, medical supplies and the overnight shipment of blood. Insurance predetermination has been denied in some cases. We do not know how many couples do not receive the needed medical treatment because of the denied insurance cover and their inability to pay themselves. Withholding treatment compromises the health of the woman and the life of fetus.

While reproductive immunotherapy is a certified programme and is provided as a non-experimental treatment, some consider the treatment controversial because conflicting results of lymphocyte immunization have been reported from various institutes. A lack of diagnostic tests defining patients who would most likely benefit from immunotherapy, a high incidence of chromosomally abnormal pregnancies and the unexplained variation in pregnancy rates of control groups may explain previous controversies. Recent reports have confirmed that allogeneic leukocyte immunization is an effective treatment for recurrent spontaneous abortion (Recurrent Miscarriage Immunotherapy Trialist Group, 1994).

Once the insurance company declares that the treatment is experimental and unnecessary, the burden of proof lies with the couples seeking cover. Insurance companies may hire ‘independent’ consultants who support their ‘experimental’ and ‘unnecessary’ assertions. The consultant remains anonymous and cannot be contacted by the couple. In addition, the plan administrator does not allow the couple to speak with the underwriter’s medical director who makes the final decision.

To make it difficult to reverse an initial denied claim, an insurance company may demand a complete copy of a patient’s medical records, including all diagnostic test results and daily treatment notes. They may require that it be shown that treatment is not in the research or experimental stage, and that the treatment does not use a drug or substance that has not been approved by the US Food and Drug Administration by issuance of a New Drug Application or other formal approval. They may require the specific published studies detailing the treatment’s success to be cited. They may want to know if the treatment is in general use by qualified physicians, and they may want a description of what medical specialities or subspecialities are qualified to give an opinion. They may request a list of contacts at other treatment centres. They may require the treatment be shown to be of demonstrated value for the diagnosis or treatment of a patient’s condition.

Fighting an insurance company requires time, energy and persistence. For couples who have experienced multiple miscarriages, a pregnancy is stressful enough without adding the stress caused by the struggle to obtain insurance cover for a needed medical treatment. It is clear that the insurance companies make it necessary to argue with them to get cover in the
majority of these cases. Even when payment is made, the insurance companies make payment based upon their determination of what is reasonable and customary.

Despite all this, there is cause for optimism. The rationale for denied claims should diminish. With the states passing infertility or family building mandates, insurance companies cannot, by law, discriminate by withholding payment for needed reproductive medical treatments. In addition, as the reproductive immunotherapy programmes continue to document their success, the experimental issues should disappear.

References


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