

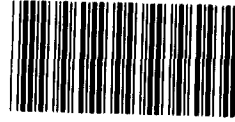
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GAO

United States  
General Accounting Office  
Washington, D.C. 20548

Human Resources Division

B-251469



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December 7, 1992

The Honorable Donald M. Payne  
Acting Chairman, Human Resources and  
Intergovernmental Relations Subcommittee  
Committee on Government Operations  
House of Representatives

Dear Mr. Chairman:

Over the past 18 months, concerns have been raised over the safety of silicone gel breast implants, which are usually inserted as part of reconstructive surgery following a mastectomy or for cosmetic purposes. Special advisory panels, convened by the Food and Drug Administration (FDA), concluded that (1) no definitive safety data exist on these implants, (2) all women should be advised of the associated risks, and (3) ruptured implants should be removed. Earlier this year, FDA placed a moratorium on the use of silicone gel breast implants, limiting their use to women in carefully controlled studies.

The Subcommittee expressed concerns that some women who are experiencing medical problems with silicone gel breast implants have been unable to have them removed due to the lack of financial resources. As agreed with the Subcommittee staff, we determined the payment practices of government and private insurers relating to the removal of breast implants. What we found out about the various insurers' payment practices is discussed in this letter.

Also in this letter, we are providing information we obtained from Medicare and state Medicaid offices on (1) the number of surgical procedures that involved the removal of breast implants, breast implant material, and other

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complications of breast implants and (2) physician charges and Medicare and Medicaid payments for such procedures.<sup>1</sup>

The Subcommittee staff also asked us to provide information on procedures that involve flap surgery--a procedure in which fat and tissue are removed from one part of the body, such as the stomach, buttocks, or back, and transplanted to the chest. The data we obtained on such procedures are presented in the enclosure.

To identify the insurers' payment practices, we contacted Medicare and Medicaid headquarters officials, Department of Defense (DOD) officials,<sup>2</sup> and representatives from the Blue Cross and Blue Shield Association (BCBS), the Health Insurance Association of America (HIAA), and the American Public Welfare Association. In addition, we contacted Medicaid offices in eight states to confirm their payment policies. The Subcommittee staff selected four of these states--Florida, Louisiana, Nevada, and Texas--and we selected the other four--California, New York, Virginia, and West Virginia--based on the availability of data.

#### RESULTS IN BRIEF

Most government and private insurers will pay for the removal of silicone gel breast implants. All insurers require that the patient's physician determine that the procedure is medically necessary. Generally, this means that the patient is suffering health problems due to the

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<sup>1</sup>We used the 1992 Physician's Current Procedural Terminology (CPT) handbook to identify these surgical procedures. The handbook is a uniform listing of medical, surgical, and diagnostic procedures performed by physicians. The procedures selected involved the removal of breast implants (code 19328) and breast implant material (code 19330), and other complications of breast implants (codes 19370 and 19371).

<sup>2</sup>The DOD health care system provides medical care to eligible active duty military personnel, military retirees, and eligible dependents of both groups. Active duty dependents, retirees and their dependents, and survivors of deceased members receive care through the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) when care is not available through military hospitals.

breast implants or that the implants have ruptured or leaked. In contrast, if breast implants are being removed solely because of emotional or psychological stress, some government and private insurers may deny coverage.

Medicare, Medicaid, DOD, and most private insurers will pay for the removal of breast implants even when the original implant is done for cosmetic purposes. However, CHAMPUS will not pay for any complications that result from breast implants done for cosmetic purposes, including the removal of ruptured or leaking breast implants.

Government officials told us that they have not heard of any beneficiaries being denied coverage for the medically necessary removal of breast implants. Moreover, only a relatively small number of requests for payment of implant removal procedures have been submitted to government insurers. However, the number paid by Medicare has increased over the past few years.

#### PUBLIC AND PRIVATE PAYMENT PRACTICES

None of the government or private insurers will pay for breast implants done for cosmetic purposes, such as augmentation. However, all the insurers, except some commercial insurers and CHAMPUS, cover removal based on medical necessity regardless of the reason for the original implant.

#### Medicare

Medicare covers services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve body functions. Medicare pays for the removal of silicone gel implants that pose a health threat and those that are ruptured or leaking. A Medicare official stated that the program covers items or services that a physician decides are medically necessary. As a result, Medicare has not developed specific guidance relating to the removal of breast implants.

#### Medicaid

Under Medicaid, states must provide for hospital and physician services, but their programs can vary. Within broad federal guidelines, each state designs and administers its own Medicaid program and sets eligibility standards and coverage policies. All eight state Medicaid

agencies that we contacted pay for the removal of breast implants, but there are some variances in approving such a procedure. For example, three states require prior authorization or peer review before approving a breast procedure. Two other states require a psychiatric evaluation before paying for the removal of implants based on emotional or psychological stress.

Louisiana's Medicaid program, for example, covers breast implants performed as part of reconstructive surgery following a mastectomy and will pay for the removal of implants when medically necessary. However, a Louisiana Medicaid official stated that, over the past several years, physicians have not submitted any claims for the removal of breast implants. Because of this inactivity, the state Medicaid claims processing system will automatically deny any claim for the removal of breast implants and implant material, or other complications of implants. The Medicaid official stated that if a physician or patient requests Medicaid to reconsider the denied claim, it will be paid if a physician determines the procedure is medically necessary.

Louisiana is considering changing its policy of automatically denying claims involving breast implant problems. Louisiana Medicaid may soon begin paying for the removal of breast implants when there is evidence of leakage. Claims for this procedure would be reviewed by medical consultants before payment is made. The Medicaid official expected that this change would be implemented.

The Texas Medicaid policy, by contrast, does not provide coverage for breast implants for augmentation purposes or following a mastectomy. All breast augmentation procedures are viewed as cosmetic surgery. In exceptional cases, coverage of breast augmentation procedures, either independently or in conjunction with a mastectomy, may be considered as a "waived exception." In these cases, a patient must demonstrate the inability to perform daily living skills and obtain prior authorization before payment is made. However, Texas Medicaid does pay for the removal of breast implants or implant material and other implant problems affecting a patient's health. The Texas policy allows coverage for complications arising from a nonapproved procedure when the complications may or do adversely affect a patient's health.

DOD

DOD's policy is to remove any breast implant affecting the patient's health, regardless of the reason for the original implant. On the other hand, CHAMPUS benefits, which are provided to military dependents and retirees, do not cover all breast implant removals.

CHAMPUS is developing a policy for the removal of silicone gel breast implants. The proposed policy, outlined in a September 1992 letter to us, stipulates that benefits for breast implant removal are not allowed if the initial surgery is not a covered CHAMPUS service. Thus, autoimmune disorders and damage, leakage, and hardening of breast implants done for cosmetic purposes are considered unfortunate consequences of a noncovered surgery. However, benefits may be allowed for a systemic infection. A CHAMPUS official stated that a blood infection would be considered a systemic infection and, if related to a breast implant, might be a basis for paying for removal even if the implant was for cosmetic purposes.

CHAMPUS officials said that no women seeking reimbursement for the removal of breast implants have been denied and there has been only one inquiry concerning CHAMPUS's reimbursement practices for the removal of implants. However, CHAMPUS's proposed policy is in direct conflict with DOD's and most other insurers' policies.

Private Insurers

Many private insurers cover the removal of breast implants. In May 1992, HIAA queried 160 medical directors of its member organizations about the (1) use of silicone gel breast implants after a mastectomy and (2) removal of these implants. The 44 medical directors, representing about 70 percent of the major underwriters of commercial insurance, who responded all said that their companies pay for breast implants as part of reconstructive breast surgery. They added that their companies also pay for the removal of such implants if deemed medically necessary. Although some companies request insurers to exclude complications arising from cosmetic surgery, most HIAA members cover the removal of silicone gel implants inserted for cosmetic purposes.

BCBS has not surveyed its member plans to determine their policies for coverage of the removal of silicone gel breast implants. Each Blue Cross and Blue Shield Plan is an

independent company that establishes its own coverage and reimbursement policies. However, a BCBS spokesperson stated that where benefits are provided for implantation of silicone gel breast implants, their medically necessary removal is usually considered a covered service.

#### Emotional or Psychological Stress

Most government and some private insurers cover the removal of breast implants based on emotional or psychological stress. Some insurers said that coverage decisions would be made on a case-by-case basis. Some Medicaid representatives said that emotional or psychological stress might not justify coverage, while others said that stress could lead to a determination of medical necessity and, therefore, would be grounds for removing breast implants. Symptoms of emotional or psychological stress could require extensive documentation. Two state Medicaid officials said that a psychiatric evaluation would have to be completed before the implant removal procedure would be covered.

The HIAA survey showed that 11 of the 44 insurers would cover the removal of silicone gel implants if the patient is suffering from psychological stress without any other medical indications or complications. A BCBS spokesperson stated that the removal of breast implants based on emotional or psychological stress has not arisen as an issue.

#### RELATIVELY FEW REQUESTS MADE TO GOVERNMENT INSURERS FOR IMPLANT REMOVAL PROCEDURES, AND NONE REPORTED DENIED

Government officials said they are unaware of program beneficiaries being denied coverage for procedures to remove silicone gel breast implants that were deemed to be medically necessary. Medicare and Medicaid officials added that, in view of the recent publicity surrounding implants, they believe that program beneficiaries would voice their concerns if coverage was denied for removal of ruptured or leaking breast implants.

A relatively few claims for breast implant removals have been submitted to Medicare, but the number is increasing. From 1989 to 1991, the number of breast implant removal claims paid by Medicare increased by 91 percent, from 270 to 517. In addition, claims involving the removal of breast implant material increased by 63 percent, from 180

to 293. In 1991, Medicare paid physicians about \$255,000 for these claims, or an average of \$309 and \$326, respectively. The Medicare payments represented about 49 percent of the amounts billed.

Medicare also covers two other surgical procedures that involve medical complications of breast implants. In 1991, Medicare paid claims for 1,270 of these breast capsule procedures,<sup>3</sup> an increase of 135 percent from 1989. In 1991, Medicare reimbursed physicians \$494,000, an average of \$389 per claim, or 45 percent of the amount physicians billed.

State Medicaid officials said few requests have been made for the removal of breast implants. For example:

- From July 1, 1991, to June 30, 1992, the California Medicaid program paid 12 claims involving the removal of breast implants or implant material. On average, the program reimbursed physicians \$258 (24 percent of the amount billed) for 8 breast implant removals and \$195 (26 percent of the amount billed) for 4 claims involving the removal of breast implant material. The program also paid physicians \$303 (21 percent of the amount billed) for another 15 claims involving problems with breast capsules.
- A Florida Medicaid official said that the number of claims involving complications of breast implants is increasing, although only a few implant removal procedures have been done. From July 1, 1990, to June 30, 1991, Florida paid one claim involving the removal of breast implant material. The next year, there were 18 claims--1 involving the removal of a breast implant, 8 involving implant material and the other 9 involving breast capsules. Between July 1 and September 30, 1992, there were 9 paid claims, 3 involving the removal of breast implants, 1 involving implant material, and 5 involving breast capsules. Physicians were reimbursed an average of \$308 for the

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<sup>3</sup>A capsule is a wall that the body forms around a breast implant. The capsule can contract, causing hardening of the implant. Surgical procedures are performed to either expand the breast pocket and relieve the hardness or remove the capsule.

breast implant removals and \$211 for the removal of breast implant material.

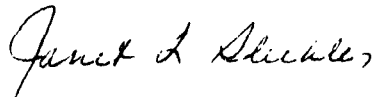
- From October 1, 1990, to September 30, 1991, New York Medicaid paid 6 claims involving the removal of breast implants, 10 claims involving the removal of breast implant material, and 4 claims involving breast capsules.
- During the period July 1991 through June 1992, Texas Medicaid paid 2 claims involving the removal of breast implants, 1 claim involving the removal of breast implant material, and 3 claims involving breast capsules.

Although data provided by state Medicaid programs cover different time periods, summarizing data from some of the larger Medicaid states can provide an indication of how many breast implant removal procedures are being paid for by Medicaid in the United States. In summary, during the periods discussed above, California, Florida, New York, and Texas, which account for about 34 percent of the Medicaid population, paid physicians for 20 breast implant removals, 25 procedures for the removal of breast implant material, and 36 breast capsule procedures.

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We will make copies of this letter available to other interested parties upon request. Please call me at (202) 512-7119 if you have any questions about the information discussed.

Sincerely yours,



Janet L. Shikles  
Director, Health Financing  
and Policy Issues

Enclosure



FLAP BREAST RECONSTRUCTION

Table I.1: Procedures Paid for by Medicare (1989-91)

Year		Type of flap procedure/CPT code			
		Muscle 19360 <sup>a</sup>	Back 19361 <sup>b</sup>	TRAM 19362 <sup>b</sup>	Free 19364 <sup>c</sup>
1989	Number of procedures	326	0	0	11
	Average Medicare payment	\$1,513	-	-	\$1,174
	Average physician bill	\$2,545	-	-	\$1,807
1990	Number of procedures	374	0	0	19
	Average Medicare payment	\$1,586	-	-	\$1,503
	Average physician bill	\$2,669	-	-	\$2,716
1991	Number of procedures	329	1	0	30
	Average Medicare payment	\$1,502	\$972	-	\$1,525
	Average physician bill	\$2,834	\$6,000	-	\$4,521

<sup>a</sup>This procedure is not listed in the 1992 CPT handbook.

<sup>b</sup>These procedures were first listed in the 1992 CPT handbook. CPT 19362 involves the use of the transverse rectus abdominis (TRAM). Medicare covers this procedure.

<sup>c</sup>Free flap surgery involves removing fat and tissue from either the stomach, buttocks, or back and transplanting it to the chest through microsurgery.

Table I.2: Procedures Paid for by Selected Medicaid States Over a 1-Year Period

State		Type of flap procedure/CPT code			
		Muscle 19360 <sup>a</sup>	Back 19361 <sup>b</sup>	TRAM 19362 <sup>b</sup>	Free 19364 <sup>c</sup>
California (July 1991-June 1992)	Number of procedures	5	d	d	0
	Average Medicare payment	\$849	-	-	-
	Average physician bill	\$4,594	-	-	-
Florida (July 1991-June 1992)	Number of procedures	3	0	0	0
	Average Medicare payment	\$1,045	-	-	-
	Average physician bill	-	-	-	-
Louisiana (July 1991-June 1992)	Number of procedures	d	0	2	d
	Average Medicare payment	-	-	\$1,549	-
	Average physician bill	-	-	\$4,860	-
New York (Oct. 1990-Sept. 1991)	Number of procedures	0	0	0	5
	Average Medicare payment	-	-	-	\$365 <sup>e</sup>
	Average physician bill	-	-	-	-
Texas (July 1991-June 1992)	Number of procedures	1	d	d	0
	Average Medicare payment	-	-	-	-
	Average physician bill	-	-	-	-

<sup>a</sup>This procedure is not listed in the 1992 CPT handbook.

<sup>b</sup>These procedures were first listed in the 1992 CPT handbook. CPT 19362 involves the use of the transverse rectus abdominis (TRAM).

<sup>c</sup>Free flap surgery involves removing fat and tissue from either the stomach, buttocks, or back and transplanting it to the chest through microsurgery.

<sup>d</sup>Not payable.

<sup>e</sup>Total Medicaid payments for these procedures.