Chapter 4

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As a result of the enactment of Public Law 96-611, in December 1980 pneumococcal vaccination became a reimbursable service under the Medicare Program, effective July 1, 1981. Pneumococcal vaccination thus became the first and to date the only preventive service paid by Medicare. With the exception of pneumococcal vaccine and its administration, the Social Security Act specifically excludes payment for preventive immunizations.

Bills to extend coverage to pneumococcal vaccine were first introduced into Congress in fall 1979. Subsequent consideration of the legislation focused on the fact that Medicare was then paying for the treatment of pneumococcal pneumonia but not for its prevention and that the vaccine had few and relatively minor side effects (60). There was also substantial interest in the financial implications for the Medicare Program. Besides the OTA cost-effectiveness analysis, a study by the Congressional Budget Office (CBO) provided relevant information. The CBO study concluded that Medicare would incur additional net costs during the initial years of coverage, but net reductions in future years. [1]

[1]The analysis was conducted including and excluding survivors' medical costs.

Since 1980, two other vaccines have been considered for Medicare coverage: hepatitis B vaccine for end-stage renal disease patients and influenza vaccine. Coverage of hepatitis B vaccine is included in the House and Senate reconciliation bills now before Congress. Inclusion of influenza vaccine was considered along with pneumococcal vaccine in 1980 and with hepatitis B vaccine in 1983. But despite the stronger statements of the Immunization Practices Advisory Committee (ACIP) regarding the advisability of influenza vaccine for elderly people (58), influenza vaccination has not become reimbursable under Medicare. Like payment of pneumococcal vaccine, the exclusion of influenza vaccination and serious consideration of hepatitis B vaccine may hinge on the implications for Medicare costs. Although hepatitis B vaccine is more expensive per dose, the Program costs of paying for hepatitis B vaccine would most likely be lower than for influenza vaccine because coverage would be limited to a much smaller number of beneficiaries, end-stage renal disease patients, rather than all aged or chronically ill ones.

IMPLEMENTATION OF MEDICARE COVERAGE

At the same time that Medicare coverage of pneumococcal vaccine was being enacted in late 1980, there was discussion in the administration about rescinding that measure. Concerns were raised about the efficacy of the vaccine and, in the early part of 1981, about the additional costs to Medicare during initial years of coverage (60). Efforts to rescind coverage were defeated in the summer of 1981.

In implementing coverage of pneumococcal vaccination, Medicare applied the same procedures as for other services covered under Part B. The Bureau of Program Operations in the Health Care Financing Administration (HCFA) notified the carriers through changes in the Carrier Reimbursement Manual (94). The carriers in turn were responsible for adjusting their systems for paying claims. Presumably special procedures were

necessary for pneumococcal vaccination because it is not subject to the deductibles and coinsurance that usually apply to **Part B** services. Although information is not available on how all of the carriers handled the change, the carrier[2] for the Commonwealth of Virginia assigned a separate procedure code to pneumococcal vaccination (75). After consulting the *American Druggist Blue Book,* that carrier has set the reimbursable charge for vaccination at **$9.60: $7.50** for the vaccine, $0.10 for the syringe, and $2 for physician time (the rate paid for injections) (17).

In January 1982, the Social Security Administration included information about coverage of pneumococcal vaccination as a "stuffer" with Social Security checks. This medium is commonly used to inform beneficiaries about notable Program changes. The notice thus appeared **6** months after coverage had begun. More importantly, it occurred in January, after the fall, the peak of public and medical concern about respiratory diseases, such as pneumonia and influenza, and it did not mention diseases, such as pneumonia, that might be prevented by the vaccine (see fig. 1).

[2]Carriers **throughout the United States set reasonable charges,** implement changes, and pay claims for Medicare Part B services.

Figure 1 .—Announcement to Beneficiaries of Medicare Coverage of Pneumococcal Vaccine, January 1982

An important message for beneficiaries who plan to work in 1982

Beginning January 1, 1982, you can earn more and still receive all your Social Security checks.

- If you are now 65 or older, or you will reach 65 in 1982, you can earn $6,000 and still receive all your checks, If your total yearly earnings go over $6,000,$1 in benefits may be withheld for each $2 of earnings above $6,000.
- If you are under 65 all of 1982, you can earn up to $4,440 and still receive all your checks. If your total yearly earnings go over $4,440,$1 in benefits maybe withheld for each $2 of earnings above $4,440.

In 1981, the annual exempt amounts were $5,500 for people 65 and over and $4,080 for people under 65.

If you worked and earned more than the annual exempt amounts in 1981 while receiving benefits, you must complete an annual report of earnings by April 15, 1982, unless you were 72 or older all year.

Note: Beginning with the month you reach age 72, you get your full check each month no matter how much you earn.

Different rules apply to people **receiving** Social Security disability or **SSI payments** if they work. Please see other side.

If you receive Social Security disability or SSI payments, you must report *all* work, no matter how much you earn. (If you are a payee for someone receiving these benefits, you must report for him or her.)

You can make your report by phoning, writing, or visiting any Social Security office. Look up "Social Security Administration" in the phone book to find the office nearest you.

pneumococcal vaccine shots

pneumococcal vaccine shots are now a covered service under Medicare. Ask your doctor's advice about your need for this vaccine.

Medical insurance deductible

Starting in 1982, the annual deductible for the medical insurance part of Medicare is $75, instead of $60.

U.S. Department of
Health and Human Services
Social Security Administration
SSA Publication No. 05-10364
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PNEUMOCOCCAL VACCINATION UNDER MEDICARE PAYMENT BY DIAGNOSIS RELATED GROUPS

Although Medicare has historically paid hospitals for the costs that they have incurred, a new system is being implemented that bases payment on the costs set in advance for diagnosis related groups (DRGs). HCFA has interpreted Public Law 98-21, which mandated DRG payment, and Public Law 96-611, which covered pneumococcal vaccination, as permitting Medicare to pay hospitals separately from the DRG system for pneumococcal vaccination. A hospital maybe reimbursed for the reasonable costs of providing pneumococcal vaccination to patients, including inpatients, who are Part B beneficiaries. The rationale is that DRG payment applies to Part A services, while pneumococcal vaccination is covered only as a Part B service. Public Law 98-21 specifically excluded physician services to hospital patients from the DRG system. Besides physician services, only two other services are covered under Part B but not Part A and hence are excluded from the DRG limits for payment for inpatients: pneumococcal vaccination and ambulance service to transfer patients from one prospectively paid hospital to another (35).

HCFA gave public notice of these decisions in the September 1, 1983, statement in the Federal Register on interim final regulations for prospective payment to hospitals. Although that notice did not include the specific implications for pneumococcal vaccination, a subsequent notice to intermediaries in October 1983 listed pneumococcal vaccination and ambulance transfer of patients as exceptions to DRG payment (29).

Although HCFA's decision was based on statutory language, the resulting payment procedure has avoided creating a financial incentive for a hospital to not provide pneumococcal vaccination. If pneumococcal vaccination were included in DRGs (as other preventive technologies are), its use would add to the hospital's costs, but not to its revenues (48). This situation is important for pneumococcal vaccination because the hospital has been suggested as an institution through which pneumococcal vaccination could be provided (22). On the basis of the percentage of patients with pneumococcal pneumonia or bacteremia who were hospitalized within the previous 3 years for any cause, Fedson has estimated that vaccinating certain patients on discharge from their previous hospitalization could avoid 10 percent of hospital admissions for all pneumonia.

ESTIMATED USE OF PNEUMOCOCCAL VACCINE

HCFA's present data systems do not permit the development of aggregate data at the national level on Part B services, such as pneumococcal vaccination (76). It is, however, an identifiable line item (a separate payment record) that the carriers submit to HCFA. New procedures are now being implemented to permit national samples of such services to be derived. HCFA is requiring all carriers to use a standard set of codes by the end of 1984 and to notify HCFA if they create new ones. Starting in July 1984, HCFA will sample the standardized data available on Part B services, and by July 1985, data from all carriers will be on the system (93).

Two sets of information do pertain to the use of pneumococcal vaccine: sales of the two vaccine manufacturers and IMS America data on physician mentions of the vaccine in the National Drug and Therapeutic Index (NDTI) and on purchases by hospitals and drug stores. The data indicate that at the most 35 percent of high-risk people have received the vaccine.

Manufacturers report sales of about 11.1 million doses of pneumococcal vaccine, net of returns, since 1978, when the first vaccine was marketed (table 6). The precise number of people at high-risk of pneumococcal disease is unknown. An approximation, however, are the people at high risk of influenza because of certain chronic conditions: diabetes, kidney disease, asthma, emphysema, tuberculosis, bronchitis, heart condition, rheumatic heart condition, hypertension, or

Table 6.—Total Sales of Pneumococcal Vaccine, Net of Returns, 1979-83

Year	Number of doses
1978	2,964,000
1979	1,565,605
1980	1,774,135
1981	2,283,240
1982	1,152,510
1983	1,313,105
Total	11,052,595

SOURCE: Unpublished data, Lederle Laboratories and Merck Sharpe & Dohme, January and February 1964.

hardening of the arteries. According to responses from a household survey, about 32 million people in the United States had such chronic conditions in 1982, including 12 million 65 years or older (table 7). If that population is indicative of the target group forpneumococcal vaccine, that vaccine has been sold for about 35 percent of the high-risk population. Including all elderly people would add 13.5 million people to the target group (87) and reduce the coverage of doses sold to about 24 percent. Including people 50 to 64 years, in accordance with the Food and Drug Administration's approved labeling, would add an additional 10.4 million to the target group for a coverage rate of 20 percent.

All of these percentages should reconsidered high estimates of use because they relate to doses sold rather than doses used. Doses sold include unknown quantities of inventories and of wastage. Since the labeling and ACIP recommend against reimmunization, it is unlikely that many people have received more than one dose.

Additional information on vaccine use comes from the NDTI of IMS America, Ltd. That survey asks a sample of physicians from a panel to indicate the pharmaceutical products related to their physician-patient encounters, regardless of location. The survey indicated that private physicians (excluding those in health maintenance organizations) had used only about 1.1 million doses of pneumococcal vaccine from 1979 to 1983 (table 8). Even after allowance for a sampling error of about 32 percent because of the small sample size (63), the figure differs markedly from manufacturers' sales, and there is no apparent explanation for the great disparity. IMS America data on purchases by hospitals and drug stores add fewer than 1 million doses (table 9). However, this data base has generally been considered more useful for qualitative as opposed to quantitative information on physician practice (40).

The NDTI data indicate several interesting patterns of use. As one would expect, primary care physicians (general or family practitioners, internists, and pediatricians) accounted for almost all of the vaccine mentions (table 10). Similarly, physicians age 50 to 64, who are most likely to have elderly patients, accounted for over half of the vaccine mentions (table 11), and patients 65

Table 7.—Persons in the United States With Certain High-Risk Conditions by Age, 1982

Years of age	Number with conditions (thousands)	Percent of total population in that age group
18-24	1,530	5
25-44	6,030	9
45-64	12,448	28
> 65	12.031	47
Total	32,039	19

[a]Conditions include diabetes, chronic kidney disease, asthma, emphysema, tuberculosis, chronic bronchitis, or chronic heart condition such as heart attack, rheumatic heart condition, high blood pressure, or hardening of the arteries.

SOURCE: Unpublished data, "U.S. Immunization Survey, 19S2," Centers for Disease Control, Division of Immunization, Atlanta, January 1984.

Table 8.—Physician Mentions of Pneumococcal Vaccine in the National Drug and Therapeutic Index (NDTI), 1979-83

Year	Number of mentions (thousands)	Percent of total
1979	160	15
1980	255	23
1981	289	26
1982	218	20
1983	170	16
Total	1,092	100

SOURCE: IMS America, Ltd., Rockville, Md., unpublished data, February 1984.

Table 9.—IMS America Data on Pneumococcal Vaccine Purchased by Hospitals and Drug Stores, 1978-82 (thousands)

	Hospitals		Drug stores	
Year	Number of doses	Dollars	Number of doses	Dollars
1978	74.8	$1,840	204.0	$ 5,012
1979	42.2	1,081	75.2	1,835
1980	46.1	1,192	65.8	1,578
1981	48.9	1,241	126.5	3,101
1982	38.6	961	105.1	2,550
Total	250.6	$6,315	576.6	$14,076

SOURCE: IMS America, Ltd., Rockville, Md., unpublished data, February 1984.

Table 10.—Physician Mentions of Pneumococcal Vaccine in the National Drug and Therapeutic Index (NDTI) by Specialty, 1979-83

Specialty	Percent
General or family practitioners	54.3
Internists	28.2
Osteopaths	6.3
Allergists	3.7
Pediatricians	3.0
General surgeons	2.7
Cardiologists	1.1
Gastroenterologists	0.3
Urologists	0.3
Ear, nose, and throat specialists	0.2
Total	100.0[a]

[a]Total may not add to 100 percent because of rounding

SOURCE IMS America, Ltd., Rockville, Md, unpublished data, February 1984

Table 11 .—Physician Mentions of Pneumococcal Vaccine in the National Drug and Therapeutic Index (NDTl) by Physician Age, 1979-83

Age	Percent
20-39	14
40-49	20
50-64	52
> 65	14
Total	100

SOURCE IMS America, Ltd., Rockville, Md, unpublished data, February 1984,

years or older accounted for 60 percent (table 12). Almost 90 percent of the vaccine mentions *were* associated with no specific diagnosis (table 13). This result may reflect that healthy people were receiving the vaccine or may simply bean artifact of the *survey* procedure,

Data from a large prepaid group practice in California are consistent with the sales reported by manufacturers. From 1979-83, the group used about 42,000 doses for its members, who consisted of about l10,000 people 65 years or older (70). Data are not available on the characteristics of the people who received the vaccine. If the members had the same rate of chronic conditions by age as the general population, which may be a high estimate, the group had vaccinated about 16 percent of its high-risk members or 13 percent if all members over 65 years are also included. That percentage would be higher to the extent that fewer high-risk people were represented in the membership,

It is difficult to identify a vaccine whose use may be compared with that of pneumococcal vaccine. Influenza vaccine is intended for similar

Table 12.—Physician Mentions of Pneumococcal Vaccine in the National Drug and Therapeutic Index (NDTI) by Patient Age, 1979-83

Age	Percent
0-2	2
3-4	1
5-24	7
25-44	4
45-64	25
65-99	61
Total	100

SOURCE: IMS America, Ltd , Rockville, Md., unpublished data, February 1984

Table 13.—Diagnoses Associated With Physician Mentions of pneumococcal Vaccine in the National Drug and Therapeutic Index (NDTI), 1979-83

Diagnoses	Percent
pneumococcal immunization	**64.7**
Immunization mixed	**24.2**
Rhinitis allergic	**1.1**
Chronic obstructive pulmonary disease	0.9
Surgery after spleen	0.8
Influenza inoculation	0.6
Allergic disorder	0.5
Emphysema without bronchitis	0.5
Perennial rhinitis	0.5
Fibrosis of lung	0.5
Disease of the mitral valve	0.5
Otitis media	0.5
Bronchiectasis	0,4
Fibroid disease of lung	0.4
Pneumonia unspecified	0.4
Hay fever with asthma	0.4
Congestive heart failure	0.2
Sinusitis allergic	0.2
Asthma allergic	0.2
Stenosis of aorta	0.1
Other	2.7
Total	100.0[a]

[a]Total may not add to 100 percent because of rounding

SOURCE IMS America, Ltd , Rockville, Md., unpublished data, February 1984

high-risk groups, primarily adults, but since it should be given every year, coverage of the target group (about 20 percent) is indicated by annual use rather than cumulative use over several years. Existing data on other vaccines pertain to those recommended for universal childhood immunization, **a** situation quite different from the selective, primarily adult use of pneumococcal vaccine. Of all the childhood vaccines, the case of mumps vaccine is the most similar to pneumococcal. By 1973, about 35 percent of the preschool population (1 to 4 years) had received mumps vaccine, which was first marketed in 1968 (21), The initial statement by the ACIP was vague, and the medical community did not promote mumps vaccine

because it did not consider the disease severe (66). Government funding for mumps vaccine began in 1973 (32), but doses sold jumped 18 percent after a multiple vaccine containing mumps, measles, and rubella was marketed in 1971 (21).

A striking feature of sales of pneumococcal vaccine is the spurt in 1981 followed by a sharp decline in 1982 (table 6). The manufacturers reported no increase in returns of vaccine during 1982. That NDTI data, which pertain to physician use rather than sales, have the same pattern suggests that the phenomenon applied to use of the vaccine, although the changes in use may have been less dramatic.

The manufacturers had undertaken public service announcements or advertising in the medical and lay publications to promote the vaccine. They reported no substantial change in expenditures between 1981 and 1982, but more may have been channeled to lay publications and less to direct promotion to physicians. The 1981 ACIP statements mentioned that pneumococcal and influenza vaccines could be administered at the same time, but the use of pneumococcal vaccine had already been much heavier in the fall, when influenza vaccine is given, than at other times of the year (table 14). Medicare's notice to beneficiaries of coverage did not appear until 1982.

The most likely explanation for the increase in 1981 was the start of Medicare coverage of pneumococcal vaccine. Although the level of promotional activities may not have changed, in 1981 the material included as a prominent feature the fact that Medicare would pay for the vaccine and its administration **(26).** In general, studies have found that the use of medical services is greater when patients bear lower costs (79). The Rand Health Insurance Study has found that this pattern applied to preventive services, which consist mostly of childhood care and prenatal services (57). However, studies specifically of immunizations have been inconsistent, with many confounding variables (79).

If Medicare coverage accounted for an increase in sales and use during 1981, that effect was transitory and not sustained even into 1982. Part of the swings may have been changes in inventories. pneumococcal vaccine does not expire for 2 years. Physicians and other providers may have ordered heavily in 1981, anticipating much greater demand because of Medicare coverage. If substantial supplies remained at the end of the year, they may have carried them over to 1982 and decreased their 1982 orders.

It is also possible that the physicians who were receptive to prevention and to pneumococcal vaccine administered it to their patients during the initial years after the vaccine became available (23). Since reimmunization is not advised, this hypothesis would predict that use would soon decline, as it did in 1982.

None of these data applies specifically to use by Medicare beneficiaries. Their use may have ranged from 5.3 million to 6.6 million vaccinations based on 20- to 25-percent use rates respectively. (The 35-percent use rate does not apply because it was derived by excluding people over age 65 who did not have certain high-risk conditions.) Assuming that people 65 years or older have received 60 percent of the vaccinations (NDTI data, table 12) also results in an estimate of 6.6 million vaccinations. At a cost of $9.60 per vaccination for 6.6 million, Medicare would have spent about $175 million on vaccination cost alone, and beneficiaries would have gained about 8,400 additional years of healthy life (see ch. 2). With savings in the cost of treating pneumococcal pneumonia and survivors' additional medical costs over time, the net Program cost in 1983 dollars would range from $37 million to $69 million.

Table 14.—Physician Mentions of Pneumococcal Vaccine in the National Drug and Therapeutic Index (NDTI) by Month, 1979-83 (percent)[a]

Month	1979	1980	1981	1982	1983
January	5	0	3	13	5
February	0	2	3	5	4
March	6	3	5	7	0
April	0	0	2	0	3
May	0	3	0	4	12
June	3	0	0	2	4
July	2	0	2	0	0
August	4	3	7	3	0
September	9	17	9	7	16
October	16	36	30	33	32
November	33	20	20	17	17
December	22	16	18	8	7
Total	100	100	100	100	100

[a]Totals may not add to 100 percent because of rounding.

SOURCE: IMS America, Ltd., Rockville, Md , unpublished data, February 1984