NATIONAL DATA SHOW SIGNIFICANT DENIALS FOR THE TREATMENT OF CANCER WITH ALPHA INTERFERON

Data covering a 21-month period reveal that many physicians across the nation are experiencing reimbursement difficulties when they prescribe alpha interferon for their patients, particularly for indications that have not been approved by the Food & Drug Administration (FDA).

The Intron A Reimbursement Information Services (IRIS), instituted by Schering Laboratories, and operated by SysteMetrics/McGraw-Hill, Inc. has been assisting physicians and their staffs with reimbursement issues relating to the treatment of patients with alpha interferon since 1987. The service provides, at the request of a physician, patient, or pharmacist, information on the clinical efficacy of alpha interferon for a particular indication, the reimbursement patterns for particular insurance carriers by region of the country, suggested letter formats for corresponding with carriers, and other related assistance. (For an indepth look at the IRIS program, see the Fall 1988 Oncology Issues, "Sources of Help for Oncologists," page 22.)

Over a 21-month period, from July 1987 through March 1989, IRIS has compiled data on the outcome of 542 calls for assistance (cases that are still pending are not included in these data).

DENIAL RATES BY PAYOR						
Type of Payor	# Cases	% Denied All Cases	% Reimbursed All Cases	% All Cases		
Federal	144	40	60	26.6		
HMO/PPO	24	21	79	4.4		
Other Public	34	9	91	6.3		
Private Payor	316	12	88	58.3		
Unknown	24	13	87	4.4		
Total All Payors	542	20	80	100.0		

Of those 542 calls, 20 percent were denied payment, despite intervention by the physician. The overall success rate of 80 percent drops dramatically, however, in those cases that were brought to the attention of the service after reimbursement was initially denied—46 percent of 112 cases were denied a second time; only 54 percent were finally approved for payment.

Federal third-party payors (Medicare and federal employee health insurance programs, e.g., Champus) had a higher denial rate than any other type of payor (see table 1 above), followed by private payors, and HMOs/PPOs. Over time,

TABLE 2

DENIALS/REIMBURSEMENTS FOR CASES PREVIOUSLY DENIED PRIOR TO SEEKING REIMBURSEMENT ASSISTANCE (Over time, by payor, all cases)

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	Last Two Quarters 1987			All Four Quarters 1988			First Quarter 1989		
Payor	Denied	Reimbursed	# Cases	Denied	<u>Reimbursed</u>	# Cases	Denied	Reimbursed	# Cases
Federal*	70%	30	20	65%	35	17	75%	25	4
HMO/PPO	50	50	2	50	50	2		0 	0
Other Public**	<u>n</u>	2 <u>1</u> 22	0	50	50	2			0
Private Payer	43	57	21	26	74	39	-	100	1
Unknown		100	1	100	1	1	10000		0

* In addition to Medicare, this category includes other federal employee health insurance programs, such as CHAMPUS.

**This category includes the Medicaid program and other expanded drug coverage programs for the elderly.

only private payors show a tendency to change their initial decision and reimburse claims. Of all cases originating in the last two quarters of 1987, 43 percent continued to be denied. Similarly, federal payors show a slight decrease in continued denials between 1987 and 1988 (70 percent to 65 percent). (See table 2).

The vast majority of reimbursement denials were for indications that have not been approved by the Food & Drug Administration (FDA). For instance, one

TABLE 3

REIMBURSEMENT RATES FOR U.S. PHARMACOPEIA-ENDORSED INDICATIONS

Indications	# of Cases	% Denied	% Reimbursed
Non-Hodgkin's Lymphoma	41	31.7	68.3
Renal Cell Carcinoma	116	26.7	73.3
Chronic Myelocytic Leukemia	59	18.6	81.4
Malignant Melanoma	48	14.6	85.4
Multiple Myeloma	59	13.6	86.4
Kaposi's Sarcoma*	56	8.9	91.1
Hairy Cell Leukemia*	32	3.1	96.9
Bladder Cancer	4	0.0	100.0

*FDA-approved indications

TABLE 4

TIME ELAPSED (IN MONTHS) UNTIL REIMBURSEMENT DECISION IS REACHED

Payor	Maximum Time	Mean Time
Federal	18.2	5.64
Other Public	18.1	5.41
HMO/PPO	10.8	4.58
Private Payor	18.9	4.55
Unknown	13.3	3.03

TABLE 5

DENIAL RATES BY PAYOR*

State	% Denied	% <u>Reimburse</u> d	Maximum Time	Mean Time	# Cases
Texas	60	40	12.4	5.35 (+.52)	10
California	56	44	18.9	5.04 (+.21)	16
New York	18	82	13.2	4.78 (05)	11
Illinois	40	60	9.8	4.57 (26)	5
New Jersey	40	60	17.5	5.10 (+.27)	10
Florida	29	71	13.1	5.39 (+.56)	7

*Percentages only for those claims that were denied prior to seeking reimbursement assistance

of the two FDA-approved cancer indications, hairy cell leukemia, was denied reimbursement in only three percent of recorded cases. However, other off-label cancer indications, endorsed by the U.S. Pharmacopeia, were denied payment in as many as 32 percent of all cases. The majority of denials were for treatment of non-Hodgkin's lymphoma (32 percent), renal cell carcinoma (27 percent), and chronic myelocytic leukemia (19 percent). (See table 3 at left). Only one off-label indication, bladder cancer, was consistently reimbursed. However, the service has only recently begun to receive calls for reimbursement assistance for bladder cancer; the IRIS data reflect only four calls to date, compared to more than 100 calls related to renal cell carcinoma.

The data also reveal a marked delay in third-parties' final resolution of claims. The mean time elapsed, for all payors, before a reimbursement decision was reached, was 4.2 months. This average length of time decreased slightly (4.0 months) for cases that were eventually reimbursed, but increased significantly (5.65 months) for cases that ultimately were denied payment.

Federal third-party payors took longer to resolve reimbursement questions (5.64 months) than any other category of payor (see table 4 at left). However, when maximum lengths of time were examined, private payors were apt to spend as much as 18.9 months to reach a reimbursement decision, compared to 18.2 for federal payors, and a low of 10.8 for HMOs/PPOs.

When previously denied cases were examined by state of origin (those states with 11 or more cases), Texas had a higher percent of continued denials than any other state (60), followed by California (56 percent), Illinois (40 percent), New Jersey (40 percent) and Florida (29 percent). The state of New York had the highest percent of cases overturned on appeal and, subsequently, reimbursed (82 percent), and also took less time to reach a reimbursement decision (a mean of 4.78 months). (See table 5 at left).

In conclusion, the data reveal that physicians who prescribe alpha interferon for their cancer patients are experiencing significant reimbursement denials, despite varied strategies to improve payment. To date, all categories of third-party payors are inclined to deny payment for off-label indications, even those indications that are endorsed by the U.S. Pharmacopeia.