STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

AGENCY FOR HEALTH CARE ADMINISTRATION,	)	
Petitioner,	)	
vs.	)	Case No. 01-4078MPI
PIERRE GASTON,	)	
Respondent.	)	

RECOMMENDED ORDER

Robert E. Meale, Administrative Law Judge of the Division of Administrative Hearings, conducted the final hearing by videoconference in Tallahassee and Miami, Florida, on January 24 and 25, 2002.

APPEARANCES

For Petitioner: Anthony L. Conticello, Senior Attorney
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For Respondent: Louise T. Jeroslow
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STATEMENT OF THE ISSUES

The issues are whether Petitioner has overpaid Respondent for medical services for which he has obtained reimbursement under the Medicaid program and, if so, by how much.

PRELIMINARY STATEMENT

By letter dated July 31, 2001, Petitioner notified Respondent that it had reviewed his Medicaid claims for specified procedures from January 1, 1996, through August 19, 2000, and determined that Petitioner had overpaid Respondent $75,387.91 for claims arising from "off-label" use of immune globulin and interleukin 2.

By Request for Formal Administrative Hearing filed September 24, 2001, with Petitioner, Respondent denied the material allegations and requested a formal hearing.

At the hearing, Petitioner stipulated that it would reduce its overpayment claim by the total of five items listed on page two of Petitioner Exhibit 27. These items, bearing a date of service of March 14, 1997, state amounts paid of $9.04, $22.41, $22.42, $1224.00, and $10.00, for a total of $1287.87. Thus, the total alleged overpayment is now $74,100.04.

At the hearing, Petitioner called three witnesses and offered into evidence 24 exhibits: Petitioner Exhibits 1-6, 8-9, 11-16, and 18-27. Respondent called one witness and offered into evidence one exhibit: Respondent Exhibit 1. All exhibits were admitted.

FINDINGS OF FACT

1. Respondent is a licensed physician engaged in the practice of medicine in Florida. From January through November

1997, Respondent worked a couple of hours each morning at the Summit Clinic in Miami before seeing patients at his own office.

2. At the Summit Clinic, Respondent administered intravenous immunoglobulin (IVIG) to adult Medicaid patients who were infected with human immunodeficiency virus (HIV). Petitioner paid the Summit Clinic, which was using Respondent's Medicaid provider number, for these and other medical services. Petitioner now claims that these IVIG services were not medically necessary, and, pursuant to its "pay-and-chase" policy, Petitioner seeks repayment from Respondent.

3. In general, the administration of IVIG transfers antibodies contained in globulin to protect the recipient from various infectious microorganisms. The United States Food and Drug Administration (FDA) has approved the marketing of IVIG for the treatment of persons with certain clinical conditions, such as idiopathic thrombocytopenic purpura, Kawasaki disease, and pediatric HIV infection.

4. However, the FDA has not approved the marketing of IVIG for the treatment of adult HIV infection. The use of a drug to treat conditions for which the FDA has not issued its approval is known as an off-label use. Some off-label uses are medically effective and prevalent, but remain unapproved by the FDA because the drug manufacturer cannot feasibly conduct expensive clinical trials generally necessary to obtain FDA marketing

approval. Despite the absence of such clinical trials, not all off-label uses are experimental.

5. In the 20 years that IVIG has been commercially available in the United States, medical researchers and practitioners have uncovered evidence in support of important off-label uses of IVIG. For instance, a common and effective off-label use of IVIG is for the treatment of Guillain-Barré syndrome. According to the University HealthSystem Consortium, the FDA estimates that 50-70 percent of IVIG use is off-label, but as much as half of the off-label use finds little, if any, support by clinical studies.

6. This case raises the question of the medical necessity of the off-label use of IVIG for the treatment of HIV-infected adults. Unlike adult-onset HIV infections, pediatric HIV infections result in systemic immune deficiencies because the children's immune systems never develop normally. In HIV-infected children, IVIG relieves the effects of these systemic immune deficiencies by preventing serious bacterial infections. For these reasons, the FDA has approved the use of IVIG for HIV-infected children.

7. By letter dated July 31, 2001, Petitioner advised Respondent that it had reviewed various Medicaid claims submitted under his provider number. As relevant to this case, the July 31 letter disallows Medicaid reimbursement for the use

of IVIG on HIV-infected adults. Stating that this use of IVIG is not "indicated" and is "investigational," the letter adds: "Medicaid policy prohibits payment for experimental procedures or non-FDA approved drugs and requires that all services rendered to Medicaid recipients be medically necessary."

8. Chapter 1 of the Physician Coverage and Limitations Handbook (Handbook) states: "Medicaid reimburses for services that are determined medically necessary . . .. In addition, the services must meet the following criteria:

> * the services must be individualized, specific, consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
>
> * the services cannot be experimental or investigational;
>
> * the services must reflect the level of services that can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide; and
>
> * the services must be furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

9. The Handbook also provides: "Medicaid does not reimburse for non-FDA approved medications. Medicaid does not reimburse procedures that are experimental or when non-FDA approved medications are included in the procedures."

10. The Medicaid Provider Reimbursement Handbook (Reimbursement Handbook) defines "experimental or clinically unproven procedures" as: "Those newly developed procedures undergoing systematic investigation to establish their role in treatment or procedure that are not yet scientifically established to provide beneficial results for the condition for which they are being used."

11. Although not directly applicable to the Medicaid program, Section 2049.4 of Chapter II, Part 3, Health Care Financing Administration Carriers Manual (HCFA Manual) states, in part:

> Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. . . . Drugs or biologicals approved for marketing by the [FDA] are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, you may pay for the use of an FDA approved drug or biological if:
>
> * It was injected on or after the date of the FDA's approval;
>
> * It is reasonable and necessary for the individual patient; and
>
> * All other applicable coverage requirements are met.
>
> * * *
>
> An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what

> is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. . . .

12. Accordingly, the Florida Medicare Local Medical Review Policy manual recognizes the use of IVIG for pediatric HIV infections, but warns: "IVIG is *not* indicated for use in adult HIV patients . . .."

13. Except for the administration of IVIG, Respondent provided state-of-the-art services to HIV-infected adults. The present record contains scant medical evidence of the effectiveness of IVIG in treating HIV-infected adults. Against considerable evidence questioning the medical necessity of IVIG in treating HIV-infected adults, Respondent offered undocumented anecdotal evidence of successful use of IVIG among his adult patients and two synopses of undisclosed preliminary data suggesting effectiveness of IVIG in HIV-infected adults. Respondent did not effectively oppose Petitioner's explanation for the differences in IVIG's effectiveness in treating adults and children, nor did Respondent offer any rationale for his claim of IVIG's effectiveness in HIV-infected adults. On this record, Petitioner has demonstrated that the use of IVIG to treat HIV-infected adults is not effective and, thus, not medically necessary.

CONCLUSIONS OF LAW

14. The Division of Administrative Hearings has jurisdiction over the subject matter. Section 120.57(1), Florida Statutes. (All references to Sections are to Florida Statutes.)

15. As the parties stipulated, Petitioner has the burden of proving that it is entitled to repayment of Medicaid payments that it has made pursuant to claims submitted under Respondent's provider number.

16. Section 409.905(9) limits reimbursements to services that are "medically necessary" for the treatment of an injury, illness, or disease. However, Section 409.905(9) prohibits reimbursements for services that are "clinically unproven, experimental, or for purely cosmetic purposes."

17. Section 409.913(1)(c) defines "medically necessary" as:

> any goods or services necessary to palliate the effects of a terminal condition, or to prevent, diagnose, correct, cure, alleviate, or preclude deterioration of a condition that threatens life, causes pain or suffering, or results in illness or infirmity, which goods or services are provided in accordance with generally accepted standards of medical practice. For purposes of determining Medicaid reimbursement, the agency is the final arbiter of medical necessity. Determinations of medical necessity must be made by a licensed physician employed by or under contract with the agency and must be

based upon information available at the time the goods or services are provided.

18. Section 409.913(10) states that Petitioner may require that a provider reimburse the Medicaid program for "inappropriate, medically unnecessary, or excessive goods or services."

19. The statutes clearly provide that Medicaid reimbursements extend only to services that are medically necessary, as determined by generally accepted standards of medical practice, and that are not clinically unproven or experimental. The statutes do not address explicitly Medicaid reimbursement for off-label uses of drugs. Nor do the statutes implicitly preclude Medicaid reimbursement for off-label uses of drugs.

20. Not all off-label uses are experimental or investigational. Off-label uses lack the clinical trials that support FDA-approved uses, but significant medical evidence other than that derived from formal clinical trials may support off-label uses. Such off-label uses are no longer experimental or investigational.

21. Not all off-label uses are medically unnecessary. Many off-label uses, such as the use of IVIG to treat Guillain-Barré, are effective. Florida statutes do not equate FDA

approval with medical necessity; instead, they refer to generally accepted standards of medical practice.

22. The Handbook reinforces the requirement of medical necessity. The Handbook's prohibition against reimbursement for non-FDA approved drugs does not prohibit reimbursement for all off-label uses; instead, it prohibits reimbursement for drugs that have not received FDA approval for any use.

23. The Reimbursement Handbook does not prohibit reimbursement for all off-label uses. The Reimbursement Handbook prohibits reimbursement for "newly developed" drugs or uses whose efficacy has not been scientifically established. Again, some off-label uses are not newly developed, but are instead supported by significant medical evidence.

24. The HCFA Manual explicitly recognizes that off-label uses may be reimbursed, if such uses are supported by medical evidence.

25. In sum, the handbooks and manuals do not enlarge upon the statutes by categorically prohibiting reimbursements for all off-label uses. Suggesting a categorical prohibition against Medicaid reimbursement only for drugs that have received no FDA approval for any use whatsoever, the handbooks and manuals allow Medicaid reimbursement for any off-label use whose effectiveness is demonstrated by medical evidence.

26. On this record, Petitioner has proved that Respondent's administration of IVIG to HIV-infected adults was not effective and thus was not medically necessary.

RECOMMENDATION

It is

RECOMMENDED that the Agency for Health Care Administration enter a final order ordering Respondent to reimburse the Medicaid program $74,100.04 in overpayments for services that were not medically necessary.

DONE AND ENTERED this 19th day of April, 2002, in Tallahassee, Leon County, Florida.

ROBERT E. MEALE
Administrative Law Judge
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Filed with the Clerk of the
Division of Administrative Hearings
this 19th day of April, 2002.

COPIES FURNISHED:

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this recommended order. Any exceptions to this recommended order must be filed with the agency that will issue the final order in this case.