



Reimbursement Guide

For the INRatio PT/INR Monitoring System

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1. About CLIA Compliance

What is CLIA?

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), are a series of federal laws that regulate laboratory testing. They were put into effect to ensure high quality, reliable, safe and accurate testing in laboratories throughout the US. Laboratory tests are classified as "waived" or "non-waived", based on the cumulative score after ranking seven different criteria by difficulty.

The HemoSense INRatio monitoring system is classified as waived status. The INRatio is easy to use, and provides accurate INR results. Testing is allowed and reimbursed only if the provider meets the requirements of the guidelines outlined by the CLIA act. To bill Medicare for laboratory tests:

- 1. The provider must have a CLIA Certificate applicable to the complexity of the testing performed, and
- 2. The CLIA number must appear on the claim.

How to get the Certificate?

CLIA applications can be obtained online from the Centers for Medicare and Medicaid Services (CMS) CLIA website, http://www.cms.hhs.gov/clia/. The site contains an updated list of waived tests with applicable codes for billing. Fill out the application and mail it back to the appropriate State Department of Health. Do not send a check with your application.

The State Department of Health will generate a coupon for the fee. As of January 1998, the fee is \$150 for 2 years. The coupon will have your CLIA ID number on it. You can mail in the fees after this and start billing using the CLIA number. Your local surveyor can advise you further.

2. Medicare Coverage

How does Medicare Reimburse?

The 2006 National Fee cap for a PT test is \$5.49. Medicare pays 100% of the allowed amount. CMS annually publishes the coverage according to a fixed fee schedule. To be eligible for coverage of coagulation tests, the Medicare beneficiary must have elected Part B coverage. Additionally, the coagulation test should meet two other requirements:

- 1. The test should be prescribed by a licensed Medical Practitioner.
- 2. The test should be medically necessary.

What is considered "medically necessary" by Medicare?

The test should be necessary for diagnosing and treating the illness or condition of the patient. That means it should not be experimental or investigational, it should be safe, effective, and provided in an appropriate setting by qualified personnel. Any procedure that screens for asymptomatic conditions is not paid.

What is the ICD-9 Code?

The necessity can be identified by using a specific International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) code. This diagnosis code documented on the claim is used by CMS to determine necessity and eventual coverage. There are many ICD-9 codes. These should be specified by the attending physician. However, for home testing, Medicare currently reimburses for mechanical heart valve replacement patients only.

V43.3 is the ICD-9-CM code for organ or tissue replaced by other means; heart valve, applies.

What CPT code should be used for the PT/INR test?

Current Procedural Terminology (CPT) codes are used to identify medical tests and procedures including laboratory tests. Modifiers are added to a CPT code to provide more information about the waived or non-waived status of the test. The CPT code for Prothrombin Time (PT) is as follows:

85610 CPT code for Prothrombin Time
OW Modifier indicating this is a waived test.

Will the finger stick be reimbursed also?

No, Medicare reimburses for venous samples but not finger sticks.

If the patient having the in-house PT test is covered by Private Insurance, you may be able to bill CPT code 36416 (Collection of capillary blood specimen e.g., finger stick, heel, ear stick) for the finger stick. Check with the insurance company for more information.

What is the reimbursement pricing for my state?

The reimbursement policies listed are those administered by CMS.

The 2006 National Fee cap for a PT test is \$5.49. All states pay this amount except:

Wyoming: \$4.44 Iowa: \$4.89 Maryland: \$5.25

Medicare billing rules generally apply to Medicaid billing but the reimbursements vary from state-to-state. Please contact private insurers directly as eligibility, coverage, billing and payment requirements may vary depending on the location and patient's plan.

What will be the deductible before claims can be reimbursed?

Medicare B covered patients must satisfy a \$100 deductible for one calendar year. Once the deductible is satisfied, the patient pays no out-of-pocket charges. The usual 20% patient co-payment does not apply to the laboratory tests.

3. States that Require Additional Regulatory Requirements with CLIA

A summary of state regulations below provides a detailed state analysis. The address and telephone number for the state regulatory office responsible for CLIA in each state are also provided in the summary. Please contact your local carrier as well as state regulatory agency to obtain a list of complete requirements for your region.

States that require CLIA registration with no other regulatory restrictions:

Alaska	Illinois	Nebraska	Texas
Arizona	Indiana	New Hampshire	Vermont
Arkansas	Iowa	North Carolina	Virginia
Colorado	Louisiana	Ohio	Wisconsin
Delaware	Michigan	Oklahoma	Wyoming
Hawaii	Minnesota	South Carolina	,

Hawaii Minnesota South Carolina Dist of Columbia Mississippi South Dakota

States that require CLIA registration and other regulatory restrictions:

• Alabama	Kansas	Montana	Oregon
California	Kentucky	Nevada	Pennsylvania
Connecticut	Maine	New Jersey	Rhode Island
Florida	Maryland	New Mexico	Utah
Georgia	Massachusetts	New York	Washington
Idaho	Missouri	North Dakota	West Virginia

4. Special Restrictions for Some States

* For most current updated regulatory information, please contact your State Department of Health.

California

Must complete CLIA and State registration forms. Call the State for registration form (213) 620-6160. Follow CLIA rules for waived testing. Personnel must meet the qualification rules for phlebotomists and testing analysts. Call Pam at (213) 576-6746 for phlebotomist's criteria (it is facility and site dependent).

Florida

Must get a "Certificate of Exemption" license from the State of Florida. Get the State and CLIA certificate at the same time. All information can be found at the following address:

http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Laboratory_Licensure/initial.shtml

Pennsylvania

Application can be found at:

http://www.dsf.health.state.pa.us/health/lib/health/clinical_laboratory_application.ps.pdf

The state has testing in three levels. An INRatio test is a LEVEL 2 test. The Medical Director must be a MD or DO and must send in CV with application with Tax Identification Number and Medical License Number. The application must be signed by both the owner and the director. The State and CLIA applications are to be sent together with all sections completed or the application will be returned to the sender. PT is required but if it is not available, split sample specimens may be used every six months. They must document QC at the frequency recommended by manufacturer. They may be required to run stability study of 10 sets of controls to show upper and lower limits. Don't start testing prior to hearing from the State. Level 2 laboratory may have an inspection. CLIA applies to Long Term Care only.

Maryland

Get a Maryland license – call Lois Feldstein (410) 402-8025 to get the state license application. She wants to talk to the laboratory to ensure they get all the necessary documents in place. Must enroll PT if available otherwise follow manufacturer's instructions. They require split sample testing twice a year if no PT testing program is available. They may get an inspection after 90 days. The regulations may be subject to change.

Nevada

Call the office of Vickie Estes, MT (ASCP) (775) 687-4475 ext. 229. The laboratory director must be MD, DO or PhD with board certification. Laboratory must follow manufacturer's recommendations, day-to-day temps, QC (two levels – can be internal/built-in), and competency assessments.

New York

Contact for questions is: James Holland, Health Program Administrator, Clinical Laboratory Evaluation Program, (518)402-4141, Fax: (518)485-5414. Community or physician owned entity: Limited service laboratory registration – follow the manufacturer's recommendations. POL: Must be owned and operated by physician(s) only – all other are limited service registration. (518) 485-5352

Required application materials may be downloaded from the following website. Go to the bold heading Limited Testing Sites and complete an Ownership & Controlling Interest Disclosure Statement (DOH-3486) and a Limited Testing Registration Form (DOH-4081) for each test site:

http://www.wadsworth.org/labcert/clep/Administrative/ChangeForms.htm

5. Summary of State Regulations

State	Contact	Address	Phone	Is CLIA Recognized?	Comments
Alabama	Faye Allen	Department of Public Health P.O. BOX 303017 Montgomery, AL 36130	334-206-5120	No	The regulation applies to clinical laboratories and hospitals, but not POLs or other medical facilities that are state licensed.
Alaska	Health Facilities Licensure Cert. 4730 Business Park Boulevard, Ste 18 Anchorage, AK 99503		907-561-8081	Yes	
Arizona	Cecilia Mesa	Arizona Dept. of Health Services 3443 North Central Suite 810 Phoenix, AZ 85012	602-364-0741	Yes	
Arkansas	Laura Moody	Division of Health Facility Services 5800 West 10th Street Little Rock, AR 77205	501-661-2201	Yes	
California	Donna McCallum	Laboratory Field Services 2151 Berkeley Way, Annex 12 Berkeley, CA 94704	213-620-6160	No (State regulations)	There are regulations that apply to laboratory testing, but a federal certificate of waiver is recognized. See above.
CLIP (CLIA equivalent for Federal Labs)		Office of Clin. Lab. Affairs Armed Forces Inst. of Path. 8403 Colesville Rd. Metro Plaza2 Suite 860 Silver Spring , MD 20910	301-295-7217	Yes	INRatio is automatically waived under CLIP.
Colorado	Yvonne Herman	Dept. of Public Health, Div. of Labs, CDH CLIA Programs P.O. Box 17123 Denver, CO 80217	303-692-3291	Yes	
Connecticut	Dept. of Public Health,		860-509-7400	No (State regulations)	Facilities performing only waived tests are exempt.
Delaware	Fred France	Office of Health Facilities, Certification and Licensure 3 Mill Road, Suite 308 Wilmington, DE 19806	302-692-3291	Yes	
District of Columbia	Solomon Yimam		202-442-4706	Yes	
Florida	Agency for Healthcare Administration		850-487-3109	No (State regulations) fdhc.state.fl.us	State regulations do not apply to waived tests. However, anyone doing waived tests is required to register with the state of Florida and pay a \$100 fee. See above .
Georgia Betty Logan Dept. of Human Resources Office of Regulatory Svcs. 2 Peachtree Street Atlanta, GA 30303		404-657-5447	CLIA and State dhr.state.ga.us	Testing regulations do not apply to physicians performing tests on their own patients. There is also an exemption for screening and monitoring tests, and Georgia recognizes the INRatio with on-board controls as an acceptable test.	
Hawaii Dept of Health Hospital and Medical Facilities Branch 1270 Queen Emma St., Suite 1100 Honolulu, HI 96813		808-692-7420	CLIA and State	State regulations do not apply to POL. Otherwise all testing must be done in the lab and collected by a qualified individual.	
Idaho	David Eisentrager Laboratory Improvement Section Bureau of Laboratories 2220 Old Penitentiary Road Boise, ID 83712		208-334-2235	Yes (State regulations)	POL and Clin Labs not waived.
Illinois	Department of Public Health Laboratory Regulations Unit 525 W. Jefferson Street, 4th Floor Springfield, IL 62761		217-782-7412	Yes	Regulations do not apply to waived tests.
Indiana Wanda Proffitt State Department of Health Division of Acute Care Svcs. 1330 W. Michigan St., Box 1964 Indianapolis, IN 46206		317-233-7502	Yes		
Iowa	Division of Health Facilities Department of Inspections		319-335-4500	Yes	

		Dept of Health and Environment	1		1
Kansas	Kansas Ruby Brower Laboratory Certification Building 740, Forbes Field Topeka, KS 66620		785-296-3811	CLIA and State Hospital	
Kentucky	Frankfort, KY 40602		502-564-2800	CLIA and State	Regulation applies only to clinical laboratories. POLs or those performing only waived tests are exempt.
Louisiana	Staci Glueck	Department of Health and Hospitals P.O. Box 3767 Baton Rouge, LA 70804		Yes	LA has state regulations, but recognize INRatio as waived.
Maine	Dept. of Health Div. of Licensing and Certification		207-287-9339	CLIA and State	
Office of Licensing & Certification		410-402-8025	CLIA and State	POL specific regs: MD can only do testing on his own patients. Must apply yearly & pay fee. QC is required they will accept INRatio's on-board QC, but we are waiting for them to put that in writing. See Above.	
Massachusetts	Pamela Stroub	Clinical Laboratory Program 305 South Street, Room 224 Jamaica Plain, MA 02130	617- 9 83-6739	No	There are state laboratory regulations that are different from CLIA. Small POL practices are exempt from the state regulation. There are also separate regulations for each health care facility type.
Michigan	Ronald Ray	Michigan Department of Public Health 3500 N. Logan, Box 30035 Lansing, MI 48909	517-241-0821	Yes	
Minnesota	Shellae/Phil Balazs	Dept. of Health Survey and Certification Division 393 N. Dunlop St., Box 64900 St. Paul, MN 55164	651-215-8704	Yes	
Mississippi	Theresa Irwin	Licensure and Certification Department of Public Health P.O. Box 1700 Jackson, MS 39215	601-576-7300	Yes	
Missouri	David Lewis	CLIA Program Bureau of Hospital Licensing and Cert. P.O. 570 Jefferson City, MO 65102	573-751-6318	CLIA and State hospital	
Montana	Ed Adams	Licensure and Cert. Bureau, Quality Assurance Division CLIA Program, Cogswell Building Helena, MT 59620	406-444-1451	CLIA and State	
Nebraska	Val Rykman (Mon and Fri only)	Consumer Safety Section Div. of Environmental Health 31 Centennial Mall S., P.O.B. 95007 Lincoln, NE 68509	402-471-8687	Yes	
Dept. of HR Bureau of Lic. and Cert., Lab. Section 1550 E. College Pkwy. Suite 15B Carson City, NV 89710		775-687-4475x 229	CLIA and State	Physicians may perform point of care tests, and medical professionals can perform tests at the patient's residence. However, all non-physician personnel must apply to the state as an office laboratory assistant. See Above.	
New Hampshire	Sylvia Miskoe		603-271-4832	Yes	
New Jersey	Department of Health CLIA Program CN 360 Trenton, NJ 08625		609-292-0016	CLIA and State	NJ has state regulations, but recognize waived tests. INRatio is on their list of waived tests.
New Mexico Julie Aragon Julie Aragon Julie Aragon Health Facilities Licensing Public Health Div., DOH 525 Camino De Los Marquez, Ste. 2 Santa Fe, NM 87501		505-841-4524	CLIA and Hospital rules		
New York	Edward Maziarz for POL Mary Aitkin for non- POL	State Dept. of Health CLIA Unit Empire State Plaza, P.O. Box 509 Albany, NY 12201	518-485-5352 518-485-5378	CLIA for POL	The state regulation applies only to Clinical Laboratories and Blood Banks. POLs, etc. come under CLIA. See Above .

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North Carolina	Raleigh, NC 27626		919-733-1610	Yes	
North Dakota	Bridget Weidner	Dept of Health & Consolidated Labs CLIA Program State Capital, 600 E. Boulevard Ave. Bismark, ND 58505	701-328-2352	CLIA and State	Regulations do not apply to physicians, nurses or phlebotomists doing "bedside screening tests" doing testing on their own patients.
Ohio	Michelle Iraabe@gw.odh.state. oh.us	Ohio DOH Laboratory Certification Branch 246 N. High St. 3rd Floor Columbus, OH 43266	614-644-1845	Yes	
Oklahoma	Dean Bay	DOH, Special Health Svcs. Medical Facilities 1000 NE 10th Oklahoma City, OK 73117	405-271-6576	Yes	
Oregon	Rita Scheu	Public Health Labs. CLIA Program Coordinator P.O. Box 275 Portland, OR 97207	503-229-5853	CLIA and State	OR is CLIA exempt, so must apply directly to state for waiver.
Pennsylvania	Marianne Porter	Department of Health Bureau of Laboratories P.O. Box 500 Exton, PA 19341	610-280-3464x 3233	CLIA and State	There are three levels of POL labs with different requirements, we are a level 2: \$125 fee, training log, procedure manual, PT, daily OC (on-board ok) and inspection are required (equivalent to moderately complex). Testing must be done under the direction of a physician. There are provisions for POC testing in nursing homes. See above.
Puerto Rico		Medicare Coordinator Department of Health Former Ruiz Soler Hospital, Road #2 Bayamon, PR 00619	8097820120	Yes	
Rhode Island	Nancy Hines	Department of Health Div. of Facilities Regulation 3 Capital Hill Providence, RI 02908	401-222-4526	CLIA and State (For public screening must have state license)	If a doctor's office is wholly owned by MDs, it is subject to CLIA but not to RI state licensure. Testing personnel either have to be licensed as Clinical Science Practitioners, or by a profession for which lab testing is in scope of practice i.e. MD, DO, RN.
South Carolina	Paula Lundy lundypv@dhec.sc.gov	Dept. of Health and Environmental Control, Bureau of Cert. 2600 Bull St. Columbia, SC 29201	803-545-4291	Yes	
South Dakota	Connie Richards	Licensure and Cert. Prog. Dept. of Health, CLIA Program 445 East Capitol Pierre, SD 57501	605-773-3694	Yes	
Tennessee	Jerry Duke	Health Care Facilities Dept. of Health and Environment 483 Plus Park Blvd. Nashville, TN 37317	615-741-7023	CLIA and State	There are laboratory regulations in Tennessee. However, they have their own list of waived tests, and PT/INR is on that list.
Texas	Rockne Demler	Health Fac. Cert. Div., Texas DOH 1100 West 49th Street Austin, TX 78756	512-834-6650	Yes	
Utah	Rebecca Christiansen	Bureau of Lab Improvement, Div. of Lab Svcs., CLIA Program 46 North Medical Drive Salt Lake City, UT 84113	801-584-8471	CLIA and Hospital rules	
Vermont	Carol Drawbaugh	CLIA Laboratory Program, Vermont DOH Lab 195 Colchester Avenue Burlington, VT 02125	802-652-4145	Yes	
Virginia	Sarah Pendergrass	Virginia DOH Office of Health Facility Regulation 3600 Center Ste. 216 Richmond, VA 23230	804-367-2107	Yes	

Washington DC		Department of Consumer and Regulatory Affairs 164 H Street NW, STE 1007 Washington, DC 20001	202-727-7200	Yes	
Washington State	Gail Neuenscwander	Office of Lab Quality Assurance Department of Health 610 NE 150th Street Seattle, WA 98155	206-361-2805		There are state regulations, but they consider INRatio waived. Customers should apply directly to them. They have a different form (deemed under CLIA). www.doh.wa.gov/lqa.htm Get application, follow manufacturer's guidelines.
West Virginia	Jerry Gross	Office of Laboratory Services 167 11 th Ave, South Charleston, WV 25303	304-558-3530		They go strictly by CLIA except facilities should notify them in writing prior to adding a new instrument or adding or deleting tests.
Wisconsin	Sharon Abraham abrahsa@dhfs.state.wi.us	Dept. of Health and Social Svcs. Clinical Lab Unit P.O. Box 309 Madison, WI 53701	608-243-2023	Yes	
Wyoming	Dewey Long	Division of Preventive Medicine CLIA program 2300 Capitol Ave., Hathaway 5th Fl. Cheyenne, WY 82002	307-777-6057	Yes	

6. Billing of E & M Codes (Physicians and Staff)

What is the reimbursement for providing services for a physician's office?

The tasks of evaluation and management of a patient's condition based on the test result are considered supporting services. These services are referred to as E&M Services. Since the physicians or their staff can perform these tests in their offices, the E&M services may be reimbursed. The difference in the amount will be based on the skills of the staff and classified as Non-Advanced Practice and Advanced Practice. The specific levels with assigned CPT codes have specific reimbursement amounts.

What qualifies as E&M Services?

These services involve the following:

- 1. Patient history documentation.
- 2. Patient examination.
- 3. Making medical decisions such as dose adjustments.

Other important features of the services rendered are providing patient care with counseling, spending time with the patient and the complexity of the decisions to be made. These factors will determine the E&M billing.

What are the E&M Service codes to be used?

99201-99205 E&M of New Patients. 99211-99215 E&M of Established Patients.

They are determined on the level of services provided. For physicians and specific advanced practitioners, a range of E&M codes is available depending on the level of services.

What is the reimbursement amount for E&M codes?

The reimbursement amount varies depending on the code used, the testing locality, and relative value units (RVUs). The ranges for the E&M codes are shown below.*

New Patients (Office or Outpatient visit)

	E & M Codes				
99201	99202	99203	99204	99205	
Simple History, Examination,	Expanded History, Examination,	Detailed History, Examination, low	Comprehensive History,	Comprehensive History,	
Decision, 10 min face-to-face.	Decision, Low to moderate severity,	complexity decision, moderate severity,	Examination, moderate	Examination, high complexity decision,	
	20 min face-to-face	30 min face-to-face	complexity decision, high severity, 45 min face-to-face	high severity, 60 min face-to-face	
\$28.94 - \$45.59	\$52.26 - \$79.59	\$77.86 - \$117.42	\$111.36 - \$164.55	\$142.96 - \$207.06	

Established Patients (Office or Outpatient visit)

	E & M Codes				
99211	99212	99213	99214	99215	
History, Examination, Decision- NA, 5 min supervision.	Problem focused History, Examination, Decision, and 10 min face-to-face.	Expanded problem focused History, Examination, low complexity decision, low to moderate severity, 15 min face-to-face.	Detailed History, Examination, moderate complexity decision, moderate to high severity, 25 min face-to-face.	Comprehensive History, Examination, high complexity decision, high severity, 40 min face-to-face.	
\$16.09 - \$28.61	\$30.20 - \$48.37	\$41.95 - \$65.35	\$66.28 - \$101.57	\$98.12 - \$144.64	

^{*2006} Medicare Fee Schedule payment rates effective January 1, 2006. The rates can be subjected to geographic adjustments and local rates will vary.

How to support the E&M Code with documentation?

The physician or staff must have a patient log sheet that shows:

- 1. Prothrombin Time was performed.
- 2. Results were made known to the patient or family member.
- 3. If any dose adjustments or additional tests were required or not.
- 4. Depending upon the risk associated with the result and problem, the options of management offered to the patient or family member.
- 5. Time spent with the patient by the physician should be documented along with the total duration of the visit.

Can the Anticoagulation Clinic also bill for E&M Codes?

Anticoagulation clinics operated by the physician and his staff can meet the E&M requirements. Hospital-owned anticoagulation clinics should contact their Reimbursement Department.

Can any other Health Professional bill the E&M Codes?

Only physicians, certified nurse practitioners, certified nurse-midwives, physicians assistants, and clinical nurse specialists can bill higher than E&M codes higher than 99211.

All other professionals can bill only at 99211 levels.

Can Pharmacists use the E& M Codes?

If the services are necessary and supervised by a physician, then they can bill under code 99211.

7. G Codes for Home Monitoring by Physicians/IDTF

List of criteria for home PT/INR monitoring:

Medicare now covers home PT/INR monitoring to patients with mechanical heart valves. The following criteria need to be met:

- Should have Mechanical Heart Valve and is on anticoagulation (warfarin) therapy for at least 12 weeks.
- 2. Should have the prescription from their doctor.
- 3. Should undergo education and training on home monitoring.
- 4. Should be testing at least once a week.

Who "manages" the dosage?

The equipment and supplies are purchased and provided by either a physician directly, to be given to his patients, or through a referral to an Independent Diagnostic Testing Facility. The IDTF will manage the provision of supplies, perform training on the use of the home monitor, and collect and provide the results called in by the patient to the physician. However it's the physician who will interpret and adjust the dose as required. The physician need not speak directly with the patient, as long as the results are documented.

How does the physician bill for home PT/INR services?

Code	Description	Medicare Amount
G0248	Demonstrate use of home PT/INR monitor	\$ 240.22
G0249	0249 Provide equipment and other test supplies \$ 143.98 for 4 tests on	
G0250	Physician's interpretation of test and patient management	\$ 9.04 for 4 tests only

2006 Medicare Physician Fee Schedule payment effective January 1, 2006 (69 Fed Reg 1083, 1267). Payment rates do not reflect geographic adjustments and local rates may vary.

How can the IDTF bill for the home PT/INR services?

The IDTF can also bill for codes G0248 and G0249, however they cannot use the code G0250, which is for physician use only.

Is the Hospital Outpatient Prospective Payment System (HOPPS) different for billing?

Yes
G0248 is allowed \$150.
G0249 is allowed \$150 per 4 tests.
Like the IDTF, G0250 is not applicable for billing.

8. Additional Resources

General Medicare Information

http://www.cms.hhs.gov/home/medicare.asp

National Coverage Analysis Decision Memo

http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=72

Prospective Payment Systems General Information

http://www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/

Physician Fee Schedule

http://www.cms.hhs.gov/PhysicianFeeSched/

Clinical Laboratory Fee Schedule

http://www.cms.hhs.gov/ClinicalLabFeeSched/

Disclaimer

The Reimbursement Guide for INRatio Monitoring System is for information purposes only. No guarantee of payment is stated or implied. It is the responsibility of the health care provider to properly code and seek reimbursement for medically appropriate and necessary services actually rendered.



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