

Notice of Independent Review Decision

August 20, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Veristat Test ~ Experimental / Investigational?

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

The physician reviewing this claim is a specialist in Medical Oncology. He is Board Certified in Internal Medicine, Board Certified in Medical Oncology and Board Certified in Hematology. He is Clinical Assistant Professor of Medicine, Department of Internal Medicine, Division of Medical Oncology/Hematology at a University. He has served as Chairman, Peer Review Committee in a healthcare network. He is a Member of the American Cancer Society as well as local and state medical associations.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

Upon independent review, the physician finds that the previous adverse determination should be upheld.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

Records Received: 40 page fax 08/01/13 Texas Department of Insurance IRO request, 243 pages of documents received via Mail on 08/16/13 URA response to disputed services including administrative and medical. Dates of documents range from 02/18/13-08/01/13.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient has a diagnosis of lung cancer. The Veristrat test has been requested.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

Veristrat is a serum proteonomics test which may allow rational drug selection (ref. 6). Initial studies of this approach are encouraging (ref. 7). Controlled trials are needed to verify the value of this approach (ref. 8 & 11). Studies are ongoing (refs. 9 & 10). Veristrat is not FDA approved but is approved under CLIA standards (ref. 14). This patient has lung cancer (refs. 12 & 13). Plan language does not provide coverage for unproven or experimental services (refs. 1, 2, 3 & 5).

There are no prospective randomized studies, national consensus statements or controlled trials demonstrating a net positive effect on health care outcomes. Under the terms of plan language, this study is unproven and experimental (refs. 1 & 3). An experimental or unproven study is not a covered benefit (ref. 2).

A medically necessary service is a service rendered in accordance with generally accepted standards of medical practice (ref. 4). Since there are no prospective randomized studies, national consensus statements or controlled trials demonstrating a net positive effect on health care outcomes, the requested service is not a service rendered in accordance with generally accepted standards.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION) *References Attached*
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)