DATE: 11/06/14

Notice of Independent Review

REVIEWER'S REPORT

DATE NOTICE SENT TO ALL PARTIES: 11.06.14

IRO CASE #:

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

M.D., board certified in Neurology with Added Qualifications in Pain Management, fellowship trained in Pain Medicine

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Proton beam radiation therapy for brain cancer

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

_____ Upheld (Agree)

__X__ **Overturned** **(Disagree)**

_____ Partially Overturned (Agree in part/Disagree in part)

Primary Diagnosis Code	*Service Being Denied*	*Billing Modifier*	*Type of Review*	*Units*	*Date(s) of Service*	*Amount Billed*	*Date of Injury*	*DWC Claim #*	*Upheld Overturn*
191.3	*77523*		*Preauth*						*Overturned*
	77421		*Preauth*						*Overturned*
	77417		*Preauth*						*Overturned*
	77427		*Preauth*						*Overturned*
	77336		*Preauth*						*Overturned*
	77263		*Preauth*						*Overturned*
	77470		*Preauth*						*Overturned*
	77321		*Preauth*						*Overturned*
	77370		*Preauth*						*Overturned*
	77290		*Preauth*						*Overturned*
	77280		*Preauth*						*Overturned*
	77293		*Preauth*						*Overturned*
	77295		*Preauth*						*Overturned*
	77300		*Preauth*						*Overturned*

PATIENT CLINICAL HISTORY (SUMMARY):

The claimant is a male who initially presented with a fever, was eventually diagnosed with glioblastoma multiforme, and underwent a right-sided craniotomy for tumor resection. Further treatment has been recommended with proton beam radiation by his oncology specialist. Reasons given for this particular form of radiation therapy are due to the proximity of the target radiation field and critical structures of the brain that are in the immediate vicinity. Compared to conventional radiation therapy, proton beam therapy has been shown to be more targeted and precise in targeting the desired tumor area, and relatively exposing normal tissues to a lesser degree of radiation. Specifically, his treating physician indicates that the use of proton beam therapy "will provide the optimum dose to targeted area, allowing for greater sparing of the normal brain tissues" and "preventing potential serious normal tissue toxicity." The claimant has actually been enrolled in

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a study that is being done to compare proton beam radiotherapy versus conventional radiotherapy for newly diagnosed glioblastoma and was randomized into the proton beam group. The treatment has been denied by the insurance carrier due to "investigational" status.

ANALYSIS AND EXPLANATION OF THE DECISION, INCLUDING CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
In addition to the materials provided for this review, additional references were also reviewed, including a document pertaining to "Adult Brain Tumors Treatment," dated 02/28/14. This reference describes proton beam therapy as "investigational," but also indicates that it carries a "theoretical advantage of delivering high doses of ionizing radiation to the tumor bed while sparing surrounding brain tissue."

Also noted is the entry of this patient's particular treatment trial, dated July 2014, sponsored and titled Glioblastoma Multiforme Proton vs. IMRT (Intensity Modulated Radiotherapy). In the description of the study, proton radiotherapy is described as "investigational" by the study sponsor.

A model policy for proton beam therapy coverage, as published by the American Society for Therapeutic Radiology and Oncology (ASTRO), dated 05/20/14, indicates that coverage for proton beam therapy is reasonable and medically necessary for "all other indications" that "are suitable for Coverage with Evidence Development (CED)." This policy further states that "as long as patient is enrolled in an IRB approved clinical trial...no indications are deemed inappropriate for CED..."

Allowance for proton beam therapy for treatment of this type of tumor has been granted by other entities. For example, the Washington State Healthcare Authority, on 07/11/14, finalized the recommendation by the Health Technology Clinical Committee that proton beam therapy be a covered benefit with conditions for CNS (central nervous system) tumors. In fact, a Local Coverage Determination (LCD), dated 11/01/14, titled L31617, which is applicable in 39 states and the Virgin Islands, indicates that proton beam therapy "will be considered medically reasonable and necessary" for several indications, including glioblastoma.

Therefore, taking all of the above into consideration, including the fact the this patient is enrolled in a clinical trial and therefore qualifies for CED designation under the ASTRO model policy, as well as the credible rationale provided by the treating physicians for the use of this therapy in this particular presentation, proton beam radiotherapy is reasonable and medically necessary in this case and should be granted approval.

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
_X___Medical judgment, clinical experience and expertise in accordance with accepted medical Standards
_____Mercy Center Consensus Conference Guidelines
_____Milliman Care Guidelines
_____ODG-Office 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):
_____Other evidence-based, scientifically valid, outcome-focused guidelines (Provide a Description)

References : as described in the above section "Analysis and Explanation ..."

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