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Notice of Independent Review Decision

DATE OF REVIEW: APRIL 24, 2009

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Previously approved and administered Reclast infusion

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

Fellow American Academy of Physical Medicine and Rehabilitation

REVIEW OUTCOME

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

Overtaken (Disagree)

Medical documentation **supports the medical necessity** of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a xx-year-old female diagnosed with osteopenia and osteoporosis. History is positive for breast cancer and Barrett's Esophagus.

In the information provided regarding Zoledronic acid (Reclast), it was noted that Reclast injection could be used in: (1) Osteopenia: a generalized reduction in

bone mass that was less severe than resulting from osteoporosis. Bone mineral density (BMD) value between -1 SD and – 2.5 SD below the young adult men.
(2) Osteoporosis: BMD value at least -2.5 SD below the young adult men.

On December 11, 2008, M.D., denied the request for Reclast infusion with the following rationale: *“The information submitted does not meet xxxx xxxxx necessity guidelines for Reclast. The member has not met criteria’s specific to: a BMD more than 2.5 standard deviations below the T-score.”*

Independent review organization (IRO) decision on December 17, 2008, upheld the appeal.

On January 13, 2009, M.D., denied the appeal for Reclast infusion with the following rationale: *“The xx Medical Policy for Reclast requires a T-score of -2.5 or less to fulfill medical necessity criteria. The prior authorization indicated that the T-score has deteriorated since 2004 with a current T-score of -2. The patient has been intolerant of oral therapy for a treatment of postmenopausal osteoporosis code 733.01. The amount of decrease of 0.8% is not significant clinically. Therefore the requested interavenous Reclast is considered not medically necessary per the xxxxx for this patient.”*

A report dated February 3, 2009, indicated the following: The original preauthorization request for Reclast infusion was denied stating that the medical necessity criteria for coverage had not been met.

On March 12, 2009, M.D., issued a letter of medical necessity stating that the patient had osteoporosis and bone density diagnosis of osteopenia. The treatment of osteoporosis included intravenous Reclast, which could be given to the patients with esophageal or other gastrointestinal (GI) disorders. The patient has a history of breast cancer – which increases the intensity of bone loss in many patients. She also had diagnosis of Barrette’s esophagus, which leads to more GI bleeds in some patients. Hence, the use of Reclast was medically necessary for treatment of osteoporosis.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION. GRANTED THE XX MEDICAL POLICY FOR RECLAST INFUSION REQUIRES A T-SCORE F -2.5 OR LESS AND THE LAST REPORTED SCORE WAS 2. HOWEVER, GIVEN THE FACT SHE IS DIAGNOSED WITH SIGNIFICANT OSTEOPENIA, OSTEOPOROSIS, BARRETTE’S ESOPHAGUS AND HISTORY OF BREAST CANCER THE REQUEST IS REASONABLE AND SHOULD BE ALLOWED AS IT IS MEDICALLY NECESSARY. THE FOLLOWING IS A CITED CRITERIA PER OSTEOPROSIS FOUNDATION:
“Patients who are not candidates for oral bisphosphonates, such as those

with severe esophageal disease, inability to remain upright, or severe cognitive impairment may be particularly suitable patients for the drug”.

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

- X MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS

- X PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE