



MedHealth Review, Inc.

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Notice of Independent Review Decision

DATE NOTICE SENT TO ALL PARTIES: 10/7/13

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

The item in dispute is the prospective medical necessity of Rituxan from June 13, 2013 to June 13, 2014.

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

The reviewer is a Medical Doctor who is board certified in Internal Medicine. The reviewer has been practicing for greater than 10 years.

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)

The reviewer disagrees with the previous adverse determination regarding the prospective medical necessity of Rituxan from June 13, 2013 to June 13, 2014.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Records were received and reviewed from the following parties:

These records consist of the following (duplicate records are only listed from one source): Records reviewed: 9/20/13 request for IRO, 6/13/13 drug request form, 5/29/13 letter, 5/21/13 physician orders, 5/31/13 physician office notes, 12/29/12 and 1/28/13 audiogram test results, Mijovec et al Autoimmune sensorineural hearing loss, Rheumatology Review 11-20, 6/14/13 denial letter, various

computer screen prints, pharmacy coverage policy for requested medication, certificate of insurance, 8/8/13 independent medical review, and 8/12/13 denial letter.

PATIENT CLINICAL HISTORY [SUMMARY]:

The member is a male who has progressive hearing loss, tinnitus and vertigo felt to be due to autoimmune disease. He has failed methotrexate and Cellcept. His condition has responded to high-dose steroids but has repeatedly recurred following a steroid taper. Rituximab was prescribed.

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

Autoimmune-mediated hearing loss is a rare condition and no drug has FDA approval for this condition or has been studied in any large randomized controlled trial. The mainstay of therapy is corticosteroids. This member is responsive to corticosteroids but has had repeated recurrence following tapering steroids. Indefinite use of high-dose steroids is not safe due to long-term corticosteroid-induced side effects. The member has additionally tried and failed appropriate next-line therapies including Cellcept and methotrexate. As with other therapies for autoimmune-mediated hearing loss, published data for use of rituximab include only case reports. That being said, an open-label study of 7 patients with this condition received 2 doses of rituximab following discontinuation of corticosteroids. Rituximab administration resulted in a sustained response, with 5 of 7 patients had at least a 10 dB improvement in hearing in one ear or improvement in word identification score of at least 12% at 24 weeks, compared to screening pretreatment values. In addition to the member failing other standard treatments and these data demonstrating efficacy of rituximab in this condition, there are no other viable treatment options in this case. In summary, rituximab is medically necessary.

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) Mijovic T et al. Autoimmune sensorineural hearing loss: the otology rheumatology interface. *Rheumatology* 2013;52:780-789

Cohen S, Roland P, Shoup A, et al. A pilot study of rituximab in immune-mediated inner ear disease. *Audiol Neurootol* 2011;16:214-21.

OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION) Micromedex