

CASEREVIEW

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Notice of Independent Review Decision

[Date notice sent to all parties]: January 22, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Oracea 40 mg (delayed-release doxycycline) (Quantity: 30/mth)

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

The Reviewer is Board Certified in Internal Medicine with over 15 years of experience.

REVIEW OUTCOME:

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

Upheld (Agree)

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

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

08/06/09: History & Physical
08/06/09: Pathology Report
08/20/09: Office Visit
08/28/09: Office Visit
05/20/10: Office Visit
05/20/10: Pathology Report
05/12/11: Office Visit
07/15/13: Progress Note
07/15/13: Pathology Report
07/22/13: Preauthorization Request
07/24/13: UR performed
08/29/13: Pathology Report
09/12/13: Progress Note
11/01/13: UR performed

PATIENT CLINICAL HISTORY [SUMMARY]:

On August 6, 2009, the claimant was seen with a chief complaint of 1. red, scaly lips which she was using Katakazole which clears it; 2. AR, uses Plexion cleanser, metrogel, Finacea gel & minocycline qod; 3. Left face before ear, black 4 mm papule mole. Assessment/Plan: 1. Lips- Acclerate oint BID, Zytex 10 mg. 2. Rosacea, change to Oracea 40 mg. 3. L preauricular.

On August 6, 2009, a pathology report indicated that the left preauricular was Seborrheic keratosis.

On May 20, 2010, refilled Oracea 40 mg #30 with 2 refills for treatment of Rosacea. Also wanted her to continue Finacea gel.

On May 20, 2010, a pathology report indicated that the sample taken below the left eye and at the center of the chest was Acrochordon.

On May 12, 2011, refilled Oracea 40 mg (indicated she could try the generic brand) and ordered continuation of the Finacea gel.

On July 15, 2013, the claimant was seen for mole and history of Rosacea. The moles were located on the back, left groin, right cheek and right hip.

On July 15, 2013, a pathology report indicated that the sample from the right cheek was Seborrheic keratosis. The sample from the left upper back was Seborrheic keratosis. The sample from under the breast was Acrochordon.

On July 22, 2013, requested Oracea 40 mg, one tablet a day. indicated a diagnosis of moderate Rosacea. He listed that Plexion cleanser (used for 6 months), Metro gel (used for 6 months), and Minocycline 100 mg (used for 6 months) as previously tried and failed for treatment of the diagnosis of Rosacea. Finacea gel was listed as being used currently. It was also indicated that the claimant had a side effect to Minocycline.

On July 24, 2013, performed a UR. Rationale for Denial: Based on the documentation provided, the patient has completed a course of therapy with the requested medication in the last 12 months.

On August 29, 2013, a pathology report indicated that the sample from the right upper thigh was Dermatofibroma. The sample from the left posterior thigh was Acrochordon.

On November 1, 2013, performed a UR. Rationale for Denial: Based on the documentation provided, the patient has completed a course of therapy with the requested medication in the last 12 months. Comments: Claims history shows previous trials of Oracea from 12/2012 – 2/2013. Previous PA added from 12/2012 – 4/2013. Tried/Failed Finacea 1/2013-10/2013, Clindamycin 3/2013, Doxycycline 7/2013-10/2013. notes member had side effects from minocycline.

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

The previous adverse determinations are upheld. Rosacea is a common and chronic inflammatory skin disease that affects many Americans. Although the phenotypes of rosacea are clinically heterogeneous, they are all related by the presence of chronic facial skin inflammation. Oracea is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. No meaningful effect was demonstrated for generalized erythema (redness) of rosacea. Efficacy of Oracea beyond 16 weeks and safety beyond 9 months have not been established.

Hence, based on medical data and literature available, use beyond 9 months is not recommended by manufacture and developer. The claimant has already completed a course of therapy with the requested medication in the last 12 months. Therefore, I uphold the decision of denial for the requested Oracea 40 mg (delayed-release doxycycline) (Quantity: 30/mth).

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