Core 400 LLC

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Review Outcome

Description of the service or services in dispute:

Compound anti-inflammatory topical cream (XX, XX, XX and XX, unspecified quantities each) XX gram XX XX, XX refills

Description of the qualifications for each physician or other health care provider who reviewed the decision:

Board Certified Orthopedic Surgeon

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

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

Patient Clinical History (Summary)

XX. XX XX is a XX-year-old XX who was injured on XX. XX was involved in a XX XX XX (XX), wherein XX sustained an injury to the XX XX and XX. XX was diagnosed with pain in unspecified joint (XX.XX), XX (XX.XX), XX XX pain (XX.XX), sprain of ligaments of XX XX, subsequent encounter (XX.XX), sprain of other part of the XX XX and XX, subsequent encounter (XX.XX), sprain of other part of unspecified XX and XX, subsequent encounter (XX.XX), sprain of medial collateral ligament of XX XX, subsequent encounter (XX.XX), sprain of medial collateral ligament of unspecified XX, subsequent encounter (XX.XX), and other sprain of unspecified XX, subsequent encounter (XX.XX).

The treatment to date included topical anti-inflammatory treatment agents (helpful). XX had failed other standard anti-inflammatories and activity modification.

Per an initial adverse determination letter dated XX by XX, the request for compound anti-inflammatory topical cream (XX, XX, XX and XX, unspecified quantities each) XX gram XX XX, XX refills was denied. Rationale: "As Official Disability Guidelines (ODG) does not recommend topical muscle relaxants, XX or anti-XX drugs for treatment of pain, and as of XX:XX XX on XX, a peer to peer could not be obtained, there is not sufficient documentation or rationale for compound anti-inflammatory topical cream (XX, XX, XX and XX, unspecified quantities each) XX gm XX XX, XX refills. Thus the requested topical compound is not approved."

Per a utilization review decision letter dated XX, the prior denial was upheld by XX. Rationale: "Regarding compound anti-inflammatory topical cream (XX, XX, XX, XX, unknown quantities each) XX g, XX refills, ODG notes that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and primarily recommended for neuropathic pain when trials of XX and XX have failed. There is no evidence for use of any other anti-XX drug as a topical product. There is no evidence for use of any other muscle relaxant as a topical product. In this case, the claimant has been diagnosed with sprain of XX XX / XX, XX xx pain, and pain in joint, XX, sprain of ligaments of XX XX, sprain of medial collateral ligaments of XX, and sprain of XX. It is noted that the claimant has failed other standard anti-

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inflammatories and activity modification and had successful conservative treatment in the past utilizing topical anti-inflammatory treatment agents. However, there is no documentation of exhausted first-line treatment, as well as evidence of objective functional improvement with prior use of topical anti-inflammatory medications. Moreover, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, non-certification is recommended."

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

The use of compounded medications are not supported as a XX line regimen for XX pain. There is no indication that the claimant had tried and failed or was intolerant to typical XX line medications used for XX pain. Further, the current evidence based guidelines do not recommend compounded medications in which certain components are not FDA approved for topical use. In this case, the components to include XX, XX, XX, and XX are not FDA approved for topical use. Therefore, it is this reviewer's opinion that medical necessity is not established and the prior denials are upheld. Given the documentation available, the requested service(s) is considered not medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the decision:

	ACOEM-America College of Occupational and Environmental Medicine
	AHRQ-Agency for Healthcare Research and Quality Guidelines
	DWC-Division of Workers Compensation Policies and Guidelines
	European Guidelines for Management of Chronic Low XX Pain
	Interqual Criteria
V	Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
	Mercy Center Consensus Conference Guidelines
	Milliman Care Guidelines
\checkmark	ODG-Official Disability Guidelines and Treatment Guidelines
	Pain Chapter/Topical Analgesics
	Not Recommended as a first-line treatment for chronic pain or osteoarthritis. Overview: XX
	Pressley Reed, the Medical Disability Advisor
	Texas Guidelines for Chiropractic Quality Assurance and Practice Parameters
	Texas TACADA Guidelines
	TMF Screening Criteria Manual

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\checkmark	Peer Reviewed Nationally Accepted Medical Literature (Provide a descriptio	n)
	Other evidence based, scientifically valid, outcome focused guidelines (Providence based)	de a description)

Appeal Information

You have the XX to appeal this IRO decision by requesting a Texas Department of Insurance, Division of Workers' Compensation (Division) Contested Case Hearing (CCH). A Division CCH can be requested by filing a written appeal with the Division's Chief Clerk no later than 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the Division.

Request for or a Division CCH must be in writing and sent to: Chief Clerk of Proceedings Texas Department of Insurance Division of Workers' Compensation P. O. Box 17787 Austin, Texas, 78744

For questions regarding the appeals process, please contact the Chief Clerk of Proceedings at 512-804-4075 or 512-804-4010. You may also contact the Division Field Office nearest you at 1-800-252-7031.