

<b>Case Number:</b>	CM13-0027141		
<b>Date Assigned:</b>	11/22/2013	<b>Date of Injury:</b>	01/14/2000
<b>Decision Date:</b>	01/30/2014	<b>UR Denial Date:</b>	08/29/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/20/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Family Practice, and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The physician reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This patient is a 54-year-old male who reported an injury on 01/14/2000. Per the documentation submitted for review, this patient is currently diagnosed with chronic constipation related to narcotic use as well as irritable bowel syndrome. Currently under consideration are requests for docusate powder 3.5 prescribed on date of service 06/07/2013, bisacodyl powder .3 gm #3, and Align 4 mg cap #28. The most recent clinical note submitted for review is dated 09/03/2013 with notes indicating that based on current assessment of the patient's symptoms and first hand evaluation of the patient weekly cognitive behavioral psychotherapy, medication and biofeedback therapy, as well as telephone consults and related psychiatric and social services, it would be necessary to treat the patient's conditions and symptoms. The patient is diagnosed with major depressive disorder of moderate severity, insomnia type sleep disorder secondary to pain, and male hypoactive sexual desire disorder due to pain. Objective clinical findings of the patient indicate stress and depression. Subjective complaints of the patient include discouragement, major depression, and pain.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**Retrospective Bisacodyl powder .3g #3 for DOS 6/7/2013: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioid Therapy, Initiating Treatment Page(s): 77.

**Decision rationale:** CA MTUS states the recommendation for prophylactic treatment of constipation at the initiation of opioid therapy. The documentation submitted for review from 06/07/2013 fails to provide a clear clinical rationale for the prescription of docusate sodium powder. Given the above, the decision for retrospective Bisacodyl powder .3g #3 for DOS 6/7/2013 is not medically necessary and appropriate.

**Retrospective Align 4mg cap #28 for DOS 6/7/2013:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Aragon, G., Graham, D. B., Borum, M., & Doman, D. B. (2010). Probiotic therapy for irritable bowel syndrome. *Gastroenterology & hepatology*, 6(1), 39.

**Decision rationale:** CA MTUS/ACOEM Guidelines do not specifically address Align Caps. Clinical literature states that probiotics will likely have an emerging adjunctive therapeutic role in treating IBS. The studies to date simultaneously provide interesting observations and raise fundamental questions. However, many of the studies involved were small in size, of short duration, and had significant design flaws. Additional issues that still need to be determined include the most effective probiotic strain, dose, and duration of therapy; whether patients should be treated for specific IBS symptoms only; and whether there is a role for maintenance IBS therapy or only IBS therapy on an as-needed basis. The documentation submitted for review from 06/07/2013 fails to provide a clear clinical rationale for the prescription of docusate sodium powder. Given the above, the decision for retrospective Align 4mg cap #28 for DOS 6/7/2013 is not medically necessary and appropriate