

## Introduction

Medical foods are increasingly being dispensed to treat cases of chronic disorders and pain associated with on-the-job injuries. Limited clinical evidence of their effectiveness, how they are regulated and ineffective measures to control dispensing, make managing medical foods challenging for workers compensation payors.

As medical foods continue to play a larger role in workers compensation, it is essential for workers compensation payors to understand their impact and develop policies for reimbursement and utilization.

Managing the Medical Foods Dilemma provides an overview of medical foods, their uses, and the role they play in workers compensation. It also provides insights on strategies workers compensation payors can use to proactively manage medical foods expenses.

## Medical Foods Defined

According to the United States Food and Drug Administration (FDA), to be classified as a medical food the food must:

- Be administered orally or through a feeding tube.
- Provide support for managing the nutrient needs resulting from a specific medical disorder, disease or condition.
- Be used under ongoing medical supervision.<sup>1</sup>

Medical foods have been primarily used for treatment of genetic diseases. They were first regulated as drugs by the FDA in the 1950s.<sup>2</sup> In 1972, the FDA revised how medical foods were regulated and reclassified them as “foods for special dietary use.”<sup>3</sup> In 1988, the modern definition of medical foods was officially established through an amendment to the Orphan Drug Act.<sup>4</sup>

### **Medical Food**

#### **U.S. Food and Drug Administration Official Definition**

. . . a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”<sup>5</sup>

Section 5b, Orphan Drug Act (21 U.S.C. 360ee (b) (3))

Today, medical foods are increasingly prescribed by doctors to treat chronic diseases, neurological disorders and other conditions. For example, medical foods are increasingly used to manage depression, sleep disorders, acute or inflammatory pain and joint disorders. They may reduce hospital stays, incidence of complications and mortality in the critically ill. Additionally, there is also evidence indicating medical foods may reduce dosage requirements of maintenance medications.

Medical foods can also be dispensed along with a generic prescription medication in the form of a convenience pack (also called a co-pack). For example, Theraproxen™ (Trepoxen) is a co-pack in which Theramine™, a medical food to help restore low levels of brain chemicals such as serotonin or gamma-aminobutyric acid (GABA) to reduce sensitivity to pain, is dispensed with naproxen, an anti-inflammatory and pain reducing medication. The purpose of the co-packaging is to replenish nutritional deficiencies, offset digestive or other side effects, enable absorption, and potentially reduce dosage of the prescribed medication. Similar to medical foods, physicians can dispense co-packs at their offices.

### Examples of Common Medical Foods

The following chart provides an overview of common medical foods, and their treatment uses.

Medical Food	Treatment Uses
Theramine™	Acute/chronic pain Neuropathic pain Fibromyalgia Inflammatory pain
Trepadone™	Joint disorders
GABAdone	Insomina Ability to fall asleep Maintaining sleep Sleep apnea
Deplin	Depression
Sentra PM	Fatigue Fibromyalgia Cognitive Impairment
Limbrel	Osteoarthritis
UltraClear Medical Food	Chronic fatigue syndrome
ProMod Liquid Protein	Wounds Stress Trauma Burns

### Classification and Regulation

Medical foods are not FDA-approved, meaning they have to undergo scientific testing, but clinical trials are not required. Additionally, individual medical food products do not have to be registered with the FDA but their ingredients do have to be Generally Recognized as Safe (GRAS). For a medical food to be considered GRAS, its ingredients must be approved food additives adequately shown to be safe under the conditions of their intended use otherwise excluded from the definition of a food additive.<sup>6</sup>

Medical foods are exempted from nutrient content and health claim labeling requirements according to the Nutrition Labeling and Education Act of 1990.<sup>7</sup> Medical food labels must conform only to general food labeling requirements including identity (the common name for the product), net quantity, manufacturer, packer and distributor, list of ingredients and major allergens according to the Food Allergen Labeling Consumer Protection Act.<sup>8</sup> All mandatory label information must be printed in English, except in United States jurisdictions where the predominant language is different.<sup>9</sup>

Manufacturers are mandated to comply with all applicable requirements for food manufacturing including: Registration of Food Facilities requirements, low acid canned food regulations, emergency permit control regulations and current Good Manufacturing Practices regulations.

While the FDA has instituted stringent guidelines on what can be classified as a medical food and how they are labeled, regulation has been fairly static since 1988.<sup>10</sup> Recently, however, the FDA issued several warning letters targeting the labeling and usage of testimonials. For example, one FDA letter concluded that a medical food did not meet the official definition because it was intended for an audience who could fulfill the nutrient requirements by modifying their diet, making the product unnecessary.<sup>11</sup> Another FDA letter concluded that the labeling on a medical food failed to bear adequate directions for the safe, intended use of the product.<sup>12</sup>

### **Role of Medical Foods in Workers Compensation**

Medical foods are increasingly being prescribed to treat cases involving chronic, neuropathic, or inflammatory pain, sleep disorders, depression, and conditions such as osteoarthritis. As a result medical foods are beginning to account for a greater portion of workers compensation medication expenses as suggested by a study recently released by the California Workers Compensation Institute (CWCI). The CWCI study found spending on medical foods and co-packs (a medical food and drug packaged and dispensed together) recently climbed dramatically -- comprising more than 12% of medication costs in the first quarter of 2009.<sup>13</sup>

There are several theories providing a rationale for a rise in the use of medical foods and co-packs<sup>14</sup> including:

- Increased marketing to physicians indicating prescribing medical foods can help doctors increase their revenue -- especially since dispensing primarily takes place at the physician's office.
- Less likely to be removed from the shelf due to how they are regulated.
- Rise in prescribing medical foods for digestive diseases and disorders such as irritable bowel syndrome (IBS) and food intolerance.
- More acceptance by physicians that nutrition plays a role in treatment of certain disorders, conditions, and diseases.
- Ability for providers, manufacturers, labelers, third-party billers, and distributors to circumvent medical fee schedules.

And while there are some indication of the benefits of medical foods -- including reduced hospital stays, improved recovery rates, and reduction in dosing of highly addictive medications -- the increase in their utilization has caused some concern in the workers compensation industry. Much of the concern is largely in part due to lack of conclusive clinical evidence to validate their effectiveness.<sup>15</sup>

For workers compensation payors, management of medical foods utilization represents a host of challenges. These include:

- Out-of-network bills since these products are often dispensed in the office by the physician.
- Co-packs are sometimes billed under one National Drug Code determined by the labeler, meaning they could be incorrectly classified or the medical food is being billed as a drug or not at all. This makes cost management tricky.
- Safety concerns for injured workers since medical foods are not required to meet stringent drug regulations.

### **Managing Medical Foods**

As medical foods and co-packs gain popularity, there are several steps payors should take to ensure effective management.

#### ***Define the Role of Medical Foods***

Clearly define a policy for how medical foods and co-packs fit into your medication plan. Determine which medical foods are appropriate for specific injury types and body parts. Also account for proper duration of use and quantity limits. If you are working with a pharmacy benefit manager (PBM), determine if they include medical foods in their formularies -- as many do not.

#### ***Claims Professional Education***

Incorporate seminars on medical foods into claims professional education and training programs. Effective seminars train and/or provide guidance to claims professionals on the payor's policies for managing medical foods. Include these topics in your seminars:

- Overview of medical foods.
- Which medical foods are included in the medication plan.
- How they are to be processed.
- Utilization management.

#### ***Properly Manage Out-Of-Network Bills***

If medical foods are allowed to be dispensed by the physician, the bills will be out-of-network. Individual bills arriving on a payor's desk are typically higher than those in the network and are usually not subject to medication utilization reviews. It also means more paperwork for claims professionals to process. It is vital for payors to have a process in place for properly driving those bills back into the network. This can be done by working with a PBM offering both paper and electronic out-of-network bill solutions.

Another method for controlling out-of-network bills related to medical foods is to educate the injured worker on the appropriate need and use of what is prescribed. There are services available to help determine if medical foods are the proper solution to addressing a diagnosis. A medical food prescription may not be needed if a more effective solution is available.

### ***Leverage Prospective and Concurrent Utilization Review Programs***

Incorporate medical foods into your existing prospective and concurrent utilization review programs. Payors working with a PBM should ensure they have a process in place that is managed by clinical pharmacists. The clinical utilization review program should use a combination of evidence-based guidelines, peer review journals, and recommendations provided by government organizations. Both prospective and concurrent review processes are essential to a successful program.

**Prospective Utilization Reviews:** A prospective program allows all involved parties to plan for future outcomes with up-front information. Historical data and practices guide future decisions at the establishment of the PBM relationship. This prospective process allows for the achievement of cost control and utilization control.

**Concurrent Utilization Reviews:** The PBM triggers concurrent alerts to inform the dispensing pharmacist about possible reasons a prescription should be questioned further prior to filling. These point-of-sale alerts may establish behaviors indicating abuse involving the use of multiple pharmacies and physicians for different medical foods, or excessive early refill attempts. The messaging from the PBM ensures prescriptions for medical foods will not be filled at the point-of-sale unless the medical food is allowed or the PBM receives authorization from the payor.

### ***Conduct Retrospective Drug Utilization Reviews And Clinical Intervention Programs***

Retrospective reviews, physician monitoring, and clinical intervention programs can continually evaluate claims for medical foods and monitor inappropriate and/or excessive use. Identifying these patterns can curtail the spending on medical foods.

**Retrospective Reviews:** After a prescription is fulfilled, a PBM's clinical pharmacist team should audit the claim for indicators of inappropriate use using these often included indicators:

- Multiple physicians.
- Duplication of therapy.
- Excessive duration and use.

These types of utilization review programs are essential to limit cases of fraud, misuse, and abuse and ultimately ensure injured worker safety. They are most effective when leveraged in conjunction with prospective and concurrent drug utilization reviews.

**Physician Monitoring:** A PBM should continually monitor the use of multiple physicians by one injured worker.

The physician monitoring program should be based on established best practices and contain multiple components including:

- Monitoring for appropriate medication utilization using evidence-based published therapeutic guidelines.
- Overseeing prescribing patterns at the physician level to establish appropriate or inappropriate use of brand name medications when an FDA approved generic equivalent exists.
- Participating in mandatory and voluntary state reporting programs that monitor for excessive prescribing patterns.

**Clinical Intervention Programs:** The PBM should have a range of clinical intervention programs to assist a client with evaluation needs. The range of programs should consist of registered pharmacists, nurses and other health professionals available for consultation on medication questions to more detailed evaluations including peer reviews and direct consultation with prescribing physicians. The PBM's clinical intervention team should provide recommendations for specific claims that require further evaluation through the use of the information gathered in prospective, concurrent, and retrospective review processes.

## Conclusion

While medical foods are fairly new to the workers compensation industry, there are strong indications that usage will continue to rise. Much of this can be attributed to an increase in prevalence of diseases warranting medical foods and the increasing number of medical foods being used for pain and psychological conditions. Medical foods are also increasing in popularity with physicians since they can be dispensed from their offices -- providing an alternative source of revenue.

These factors make it critical for workers compensation payors to take action now to put strategies for managing medical foods into place. Doing so, ultimately ensures injured worker safety and reduces the total cost of the claim.

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### About Progressive Medical

Progressive Medical offers cost management services and programs to the workers compensation industry. By combining its clinical expertise with access to an expansive network of pharmacies, home health care services and medical equipment and supplies, the company enables its clients to manage costs while providing quality care to injured workers. Learn more at [www.progressive-medical.com](http://www.progressive-medical.com) or call 800.777.3574.

