
Oregon Health Resources Commission



SKELETAL MUSCLE RELAXANTS

Update Report

Update #1, March 2004

This report is an update of the initial
Skeletal Muscle Relaxant Subcommittee
Report of August 2003.
All revisions are highlighted.

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Overview

The 2001 session of the Oregon Legislature passed Senate Bill 819, authorizing the creation of a Practitioner-managed Prescription Drug Plan (PMPDP), that specifically directs the Health Resources Commission (HRC) to advise the Department of Human Services (DHS) on this Plan.

In November of 2002 the Oregon Health Resources Commission (HRC) appointed a subcommittee to perform an evidence-based review of the use of skeletal muscle relaxants. Members of the subcommittee consisted of physicians, a pharmacist, other health care professionals and a consumer. The subcommittee had four meetings held in public with appropriate notice provided.

Subcommittee members worked with Oregon Health and Science University (OHSU) Evidence-based Practice Center (EPC) to develop and finalize key questions for this drug class review, specifying patient populations, medications to be studied and outcome measures for analysis, considering both effectiveness and safety. Evidence was specifically sought for subgroups of patients based on race, ethnicity and age, demographics, other medications and co-morbidities.

Using standardized methods, the EPC reviewed systematic databases, the medical literature and dossiers submitted by pharmaceutical manufacturers. Inclusion and exclusion criteria were applied to titles and abstracts, and each study was assessed for quality according to predetermined criteria.

The OHSU EPC's draft report, *Drug Class Review on Skeletal Muscle Relaxants* was completed February 14, 2003, circulated to subcommittee members and posted on the Oregon Health Policy & Research (OHPR) web site at <http://www.ohpr.state.or.us>. The subcommittee met on March 18, 2003, to review the document and additional evidence. By consensus, the subcommittee members agreed to adopt the EPC report. Time was allotted for public comment, questions and testimony. The subcommittee's final meeting was held on April 16, 2003 to accept the EPC's updated report of April 9, 2003 *Drug Class Review on Skeletal Muscle Relaxants* and review the draft subcommittee report. All available sources of information from the EPC's report that included information submitted by pharmaceutical manufacturers and public testimony were considered. The conclusions drawn by the Skeletal Muscle Relaxant Subcommittee comprise the body of this report.

The HRC appointed an update committee to perform an evidence-based review of the June 2002 *Skeletal Muscle Relaxant Subcommittee Report* for new information or changes in the FDA package inserts. Members of the Update Committee consisted of one HRC member, one OSU pharmacist, one Oregon Health Policy and Research (OHPR) physician, one OHSU-EPC pharmacist, and two Skeletal Muscle Relaxant Subcommittee members. The committee held one meeting held in public with appropriate notice provided.

This report is an update of the initial April 2003 Subcommittee Report. All revisions are highlighted.

The Skeletal Muscle Relaxant Update Committee members worked with the OHSU-EPC reviewing the evidence for both effectiveness and safety. Evidence was specifically sought for differences among subgroups of patients based on race, ethnicity, age, demographics, other medications and comorbidities.

The OHSU EPC's draft report, *Preliminary Update Drug Class Review on Skeletal Muscle Relaxants for Spasticity and Musculoskeletal Conditions* was completed in January 2004, circulated to committee members. The update committee held one meeting to review the document and additional evidence. By consensus, the committee members agreed to adopt the EPC report. Time was allotted for public comment, questions, and written and oral testimony. All available sources of information from the EPC's report that included information submitted by pharmaceutical manufacturers and public testimony, were considered.

This report is prepared to facilitate the HRC in providing recommendations to Oregon Medical assistance Program (OMAP) for the Plan Drug List (PDL). This report was presented to the HRC on February 20, 2004 at which time public testimony was heard and due consideration given. On February 20, 2004 this report was approved by the HRC and commended to OMAP.

This report does not recite or characterize all the evidence that was discussed by the OHSU EPC, the Skeletal Muscle Relaxant Subcommittee, the Update Committee or the HRC. For further information provided during the subcommittee process readers are encouraged to review the source materials on the web site.

The Skeletal Muscle Relaxant Update Committee of the HRC, working together with the EPC, Oregon Medical Assistance Program (OMAP), and the Oregon State University (OSU) College of Pharmacy, will monitor medical evidence for new developments in this drug class. Approximately every six months emerging pharmaceuticals will be reviewed and if appropriate, a recommendation for inclusion in the PMPDP will be made. Significant new evidence for pharmaceuticals already on the PMPDP will be assessed and Federal Drug Administration (FDA) changes in indications and safety recommendations will be evaluated. The Skeletal Muscle Relaxant report will be amended if indicated. Substantive changes will be brought to the attention of the Health Resources Commission, who may choose to approve the report, or reconvene a new Skeletal Muscle Relaxant Subcommittee.

The initial and updated OHSU EPC's draft report, *Drug Class Review on Skeletal Muscle Relaxants*, are both available on the Office for Oregon Health Policy & Research, Practitioner-Managed Prescription Drug Plan website:

www.oregonrx.org. Information regarding the Oregon Health Resources Commission and its subcommittee policy and process can be found on the Office for Oregon Health Policy & Research website: www.ohpr.state.or.us. You may also request more information including copies of the draft report, minutes and tapes from:

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Information dossiers submitted by pharmaceutical manufacturers are available upon request from the OHSU - Center for Evidence-based Policy by contacting:

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There will be a charge for copying and handling in providing documents both from the Office of Oregon Health Policy & Research and from OHSU Center for Evidence-based Policy.

Critical Policy:

- *Senate Bill 819*
 - “The Department of Human Services shall adopt a Practitioner-managed Prescription Drug Plan for the Oregon Health Plan. The purpose of the plan is to ensure that enrollees of the Oregon Health Plan receive the most effective prescription drug available at the best possible price.”
- *Health Resources Commission*
 - “Clinical outcomes are the most important indicators of comparative effectiveness;”
 - “If evidence is insufficient to answer a question, neither a positive nor a negative association can be assumed.”

Introduction:

Skeletal muscle relaxants are a heterogeneous group of medications that are commonly used to treat two different types of underlying conditions: spasticity from upper motor neuron syndromes and muscular pain or spasms from peripheral musculoskeletal conditions. Although these drugs have been classified into one class, the Food and Drug Administration (FDA) has approved only baclofen, dantrolene, and tizanidine in this class for the treatment of spasticity; tizanidine and the remainder of the skeletal muscle relaxant class are approved for treatment of musculoskeletal conditions.

Spasticity is a clinical condition that is “a motor disorder characterized by increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyper-excitability of the stretch reflex, as one component of the upper motor neuron syndrome.”¹ Spasticity from the upper motor neuron syndrome can result from a variety of conditions that affect the brain or the spinal cord such as: multiple sclerosis, spinal cord injury, traumatic brain injury, cerebral palsy, and post-stroke syndrome. In many patients with these chronic conditions, spasticity can be disabling and painful with a marked effect on their functional ability and quality of life.

Common musculoskeletal conditions causing tenderness and muscle spasms include fibromyalgia, tension headaches, myofascial pain syndrome, and mechanical low back or neck pain. In these conditions, muscle spasm is related to local factors involving the affected muscle groups. There is no increased tone or reflex. These conditions are usually acute and occur more commonly than spasticity in clinical practice. They can cause significant disability and pain in some patients. Skeletal muscle relaxants are one of several classes of medications such as anti-inflammatory drugs and pain relievers that are used to treat these conditions.

Inclusion Criteria:

- *Scope*
 - Patients: Adult or pediatric patients with:
 - A) Chronic neurological conditions associated with spasticity (including cerebral palsy, multiple sclerosis, traumatic brain injury, spinal cord injury, post-stroke),
 - B) Chronic or acute musculoskeletal condition associated with muscle spasms (including fibromyalgia, tension headaches, low back pain, myofascial pain syndromes and nocturnal leg cramps), or

¹ Lance, JW. Symposium synopsis. In: Feldman, RG, Young RR, Koella WP, editors. Spasticity: disordered motor control. Chicago: Yearbook Medical; 1980. p. 485-494

- C) Chronic or acute pain condition with muscle spasms (including fibromyalgia, tension headaches, low back pain, and myofascial pain syndromes).

■ *Interventions*

- Baclofen, carisoprodol chlorzoxazone, cyclobenzaprine, dantrolene, metaxalone, methocarbamol, orphenadrine, quinine, tizanidine, clonazepam*, clonidine*, clorazepate*, diazepam*, and gabapentin*, (*Drugs of another class used for comparison only).
- For effectiveness: Controlled clinical trial comparing an included muscle relaxant with: 1) another included muscle relaxant; 2) another oral agent or placebo.
- For safety: Controlled clinical trials or observational studies.
- For duration: Chronic neurological conditions, at least 4 weeks of study; musculoskeletal conditions, any duration.

■ *Outcomes*

- Relief of muscle spasms or pain, functional status, quality of life, withdrawal rates, or adverse effects (including sedation, addiction, and abuse). Exclude: Non-clinical outcomes.

■ *Exclusions*

- Obstetric patients
- Chronic pain conditions without muscle spasm
- Restless leg syndrome
- Studies of less than 4 weeks in duration evaluating patients with a chronic neurological condition

Drugs:

■ *Muscle Relaxants*

<u>Generic</u>	<u>Brand</u>
- Baclofen	Baclofen
- Carisoprodol	Soma
- Chlorzoxazone	Parafon Forte
- Cyclobenzaprine	Flexeril
- Dantrolene	Dantrium

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- | | |
|-----------------|----------|
| - Metaxalone | Skelaxin |
| - Methocarbamol | Robaxin |
| - Orphenadrine | Norflex |
| - Quinine | Quinine |
| - Tizanidine | Zanaflex |

Key Questions

1. What is the comparative efficacy of different muscle relaxants in reducing symptoms and improving functional outcomes in patients with a chronic neurological condition associated with spasticity, a chronic or acute musculoskeletal condition associated with muscle spasms, or a chronic or acute pain condition with muscle spasms?
2. What are the comparative incidence and nature of adverse effects (including addiction and abuse) of different muscle relaxants in patients with a chronic neurological condition associated with spasticity, a chronic or acute musculoskeletal condition associated with muscle spasms, or a chronic or acute pain condition with muscle spasms?
3. Are there subpopulations of patients for which one muscle relaxant is more effective or associated with fewer adverse effects?

New Findings of SMR Update Committee, January, 2004

In the process of revising the February 14, 2003 Drug Class Review of Skeletal Muscle Relaxants for Spasticity and Musculoskeletal Conditions, for its submission in June 2003, the EPC identified six placebo controlled trials of patients with musculoskeletal conditions and one placebo-controlled trial of patients with spasticity. Two fair quality placebo-controlled trials evaluated the efficacy of metaxalone in low back pain² and one poor quality placebo-controlled trial unspecified skeletal muscle disorders.³ One fair quality trial evaluated the efficacy of tizanidine in patients with chronic tension headaches.⁴ One fair quality trial evaluated cyclobenzaprine in patients with fibromyalgia.⁵ One trial evaluated the efficacy of methocarbamol in patients with nonspecific muscle pain

² Fathie K. A second look at a skeletal muscle relaxant: A double-blind study of metaxalone. *Current Therapeutic Research* 1964;6(11):677-683

³ Dent RW, Ervin DK, 1975. A study of metaxalone (Skelaxin) vs. placebo in acute musculoskeletal disorders; a cooperative study. *Current Therapeutic Research, Clinical & Experimental*. 1975;18(3):443-440.

⁴ Saper, JR, Lake AE, Cantrell DT et al. Chronic daily headache prophylaxis with tizanidine: a double-blind, placebo-controlled, multicenter outcome study. *Headache* 2002;42(6):470-482

⁵ Quimby LG, Gratwick GM, Whitney CD et al. A randomized trial of cyclobenzaprine for the treatment of fibromyalgia. *Journal of Rheumatology Supplement* 1989;19:140-3.

and spasms.⁶ One trial that evaluated skeletal muscle relaxants in patients with spasticity was a poor quality trial of methocarbamol in children with cerebral palsy.⁷

There was enough evidence from a study summarizing case reports to suggest an association of chlorzoxazone with hepatotoxicity.⁸ This study evaluated 23 cases reported to the FDA since 1970 in addition to the case observed by the authors in 1986. Eight cases (two fatal) were judged to be probably related to chlorzoxazone, while the rest were possibly or doubtfully related. Most cases were mild and resolved after discontinuation of the medication. There was no data estimating rates of serious hepatotoxicity in patients treated with chlorzoxazone.

In the recent update searches performed in October 2003, the EPC found 590 citations from Cochrane Central Register of Controlled Trials, Medline, and Embase of which 31 were randomized controlled trials. Only 2 of these trials fulfilled inclusion criteria.⁹ Both included trials were short term (7 days), rated fair for internal validity and adverse event assessment. One trial evaluated the efficacy and adverse events of cyclobenzaprine 5 mg po tid and 10 mg po tid compared to placebo. It found that the two regimens were equivalent, but the lower dosage was superior for adverse events. The second trial compared 2.5 mg po tid and 5 mg po tid compared to placebo. It found that the 2.5 mg regimen was no different than placebo for efficacy though it was associated with fewer adverse events. The authors concluded that the 5 mg tid dose of cyclobenzaprine might maximize clinical effectiveness while minimizing adverse events.

A recent systematic review evaluating the effectiveness of skeletal muscle relaxants and benzodiazepines for acute nonspecific low back pain does not appear to change the results of the original report. The review was not designed to specifically assess comparative efficacy, but “found that the various muscle relaxants were similar in performance.”¹⁰

Based on additional trials reviewed and incorporated into the report in June 2003, and two other trials and a systematic review identified in update searches performed in October 2003, there does not appear to be new evidence that would significantly change the conclusion of the original report. No new head-to-head trials were identified, and none of the placebo-controlled trials identified since the original report were rated good quality.

⁶ Tisdale SAJ, Ervin DK. A controlled study of methocarbamol (Robaxin) in acute painful musculoskeletal conditions. *Current Therapeutic Research, clinical & Experimental* 1975;17(6):525-530.

⁷ Bjerre I, Blennow G. Methocarbamol in the treatment of cerebral palsy in children. *Neuropadiatrie* 1971;3(2):140-6.

⁸ Powers BJ, Cattau EL, Zimmerman HG. Chlorzoxazone hepatotoxic reactions. An analysis of 21 identified or presumed cases. *Archives of Internal Medicine* 1986;146(6):1183-1186

⁹ Borenstein DG, Korn S. Efficacy of low-dose regiment of cyclobenzaprine hydrochloride in acute skeletal muscle spasms: results of two placebo-controlled trials. *Clinical therapeutics* 2003;25(4):1056-73.

¹⁰ van Tulder MW, Touray T, Furlan AD et al. Muscle relaxants for nonspecific low back pain; A systematic review within the framework of the Chchrane collaboration. *Spine* 2003;28(17):1978-1992.

Amended Summary of Results

Key Question 1 **What is the comparative efficacy of different muscle relaxants:**

A. For reducing symptoms and improving functional outcomes in patients with a chronic neurological condition associated with spasticity?

Three systematic reviews, of which only one was good quality that addressed spasticity in patients with Multiple Sclerosis, showed insufficient evidence to compare tizanidine, baclofen, dantrolene, or diazepam due to the marked heterogeneity in study designs, interventions, and outcomes measured. Two meta-analyses of unpublished studies of fair quality concluded there were no differences between tizanidine and diazepam or baclofen. Seventeen head-to-head trials, of which most were only fair quality, revealed no difference between tizanidine vs. baclofen. Another eight head-to-head trials compared tizanidine, baclofen, dantrolene, and diazepam and found no difference for efficacy. Of the 36 placebo-controlled trials identified, no conclusions about comparative efficacy could be drawn from these trials.

Diazepam was used for comparison only and not directly evaluated. Diazepam belongs to the benzodiazepam class of drugs that are classified as tranquilizers rather than a muscle relaxant. Since tranquilizers are considered a mental health drug, the HRC is prohibited by SB 819 from evaluating their efficacy.

B. For reducing symptoms and improving functional outcomes in patients with a chronic or acute musculoskeletal condition associated with muscle spasms?

One good quality systematic review in patients with back pain concluded that cyclobenzaprine was superior to placebo. One fair quality meta-analysis of unpublished short-term trials with a variety of musculoskeletal conditions concluded that cyclobenzaprine and diazepam were equivalent and better than placebo. Eleven head-to-head trials of fair quality that compared: tizanidine vs. chlorzoxazone, cyclobenzaprine vs. carisoprodol, cyclobenzaprine vs. methocarbamol, carisoprodol vs. diazepam, cyclobenzaprine vs. diazepam, tizanidine vs. diazepam showed no clear evidence that any muscle relaxant was superior for efficacy. There is fair quality evidence from 20 placebo controlled trials that cyclobenzaprine is more effective than placebo. The body of evidence regarding tizanidine (7 trials), carisoprodol (4 trials), orphenadrine (4 trials) and methacarbamol (2 trials) was not as robust, yet with each of these interventions there was a consistent trend favoring the active treatment compared to placebo. The duration of all the studies were short in the head-to-head trials ranging from 7 to 18 days. Metaxalone was shown to be effective in two of the three available placebo-controlled trials.

Diazepam was used for comparison only and not directly evaluated. Diazepam belongs to the benzodiazepam class of drugs that are classified as tranquilizers

rather than a muscle relaxant. Since tranquilizers are considered a mental health drug, the HRC is prohibited by SB 819 from evaluating their efficacy.

C. *For reducing symptoms and improving functional outcomes in patients with a chronic or acute pain condition with muscle spasms?*

None of the reviews, trials, or observational reports separated the patients with chronic or acute pain with muscle spasms from the patients with muscle spasm or spasticity alone.

Consensus

The subcommittee agrees by consensus that the evidence does not support a difference between the comparative efficacies of baclofen, dantrolene, or tizanidine for spasticity associated with chronic neurological conditions.

The evidence does not support a difference between the comparative efficacies of any of the skeletal muscle relaxants for muscle spasm.

Nearly all the studies for musculoskeletal conditions were limited to short-term treatment and showed only a modest clinical effect. Cyclobenzaprine had the largest body of evidence to support its efficacy. Metaxalone was not shown to be effective.

Key Question 2

What are the comparative incidence and nature of adverse effects (including addiction and abuse) of different muscle relaxants?

A. *For patients with a chronic neurological condition associated with spasticity?*

Eight head-to-head trials with fair evidence of adverse event assessments did show that baclofen was associated with more weakness and less dry mouth than tizanidine, but no conclusions as to the safety of dantrolene compared to baclofen and tizanidine could be drawn. Two observational studies reported rare but serious dose related hepatotoxicity from dantrolene resulting in a black box warning in the Physicians Desk Reference. Both tizanidine and dantrolene require monitoring of liver enzymes to identify hepatotoxicity. There were no reports of addiction for tizanidine, baclofen, or dantrolene; although there have been clinical reports of severe symptoms with the sudden withdrawal of baclofen, particularly intrathecally administered Baclofen.

B. *For patients with a chronic or acute musculoskeletal condition associated with muscle spasms?*

There was very limited adverse event data for skeletal muscle relaxants from head-to-head, placebo-controlled trials, or observational studies. There are reports of potential addiction with carisoprodol since its known metabolite is meprobamate that is a schedule IV controlled substance.

There appear to be very rare cases of hepatotoxicity with two fatalities out of 23 reported cases associated with chlorzoxazone, but the rate of complications could not be calculated from the reviewed study.

One new fair quality randomized controlled trial found that cyclobenzaprine 5 mg tid provided equivalent effectiveness to 10 mg tid regiment, yet was associated with fewer adverse events. This could guide optimum dose recommendations and similar information would be useful for other skeletal muscle relaxants.

In spite of diligent efforts of the EPC and our sub-committee, no evidence of systematic reports of addiction or abuse from skeletal muscle relaxants were available, although anecdotal evidence would suggest such tendencies.

C. For patients with a chronic or acute pain condition with muscle spasms?

None of the reviews, trials, or observational reports separated the patients with chronic or acute pain with muscle spasms from the patients with muscle spasm or spasticity alone.

Consensus

The subcommittee agrees by consensus that there is sufficient evidence to conclude that there are different nuisance side effect profiles associated with baclofen, dantrolene, or tizanidine. Dantrolene is associated with rare but fatal hepatotoxicity and tizanidine requires monitoring of liver function tests as it may also pose a risk for hepatotoxicity.

The evidence does not support any conclusions about the comparative safety of any of the skeletal muscle relaxants in patients with musculoskeletal conditions. There appear to be very rare cases of hepatotoxicity with two fatalities potentially associated with chlorzoxazone, but the rate of complications could not be calculated from the reviewed study.

There was insufficient evidence of the comparative risk of abuse or addiction with skeletal muscle relaxants, but the subcommittee notes that only carisoprodol and its active metabolite, meprobamate, are Schedule IV controlled substances in Oregon, although Meprobamate is not a federally Schedule IV controlled substance.

Key Question 3

Are there subpopulations of patients for which one muscle relaxant is more effective or associated with fewer adverse effects?

There were no studies designed to compare efficacy for different races, genders, or age groups. All of the data reviewed for the spasticity drugs were from adult trials. Most of the data on musculoskeletal conditions was collected on patients with low back symptoms, neck syndromes, or multiple sclerosis.

Consensus

The subcommittee agrees by consensus that the evidence does not support any conclusions as to the comparison of the efficacy or adverse effects for different subpopulations of patients such as race, gender, or age.

Conclusion

In a series of public meetings with the opportunity for public questions, comment and testimony, the Skeletal Muscle Relaxants Subcommittee of the Health Resources Commission reviewed the medical evidence comparing Skeletal Muscle Relaxants. The Oregon Evidence-based Practice Center's report, "Drug Class Review on Skeletal Muscle Relaxant Drugs," which included appropriate information presented in pharmaceutical manufacturer dossiers, was reviewed and public testimony considered. Most skeletal muscle relaxants were evaluated for either spasticity or musculoskeletal conditions; only tizanidine was evaluated in head-to-head and more than two placebo-controlled trials for both spasticity and musculoskeletal conditions.

Using all of these sources of information, the subcommittee arrived at the following conclusions about the comparative effectiveness and safety of skeletal muscle relaxants as supported by analysis of the medical literature:

CONCLUSION

It is the decision of the Skeletal Muscle Relaxant Subcommittee that:

- *The evidence does not support any conclusions about the comparative effectiveness between baclofen, tizanidine, or dantrolene for spasticity. All are effective and equivalent to diazepam. Dantrolene is associated with rare serious dose-related hepatotoxicity.*
- *The evidence does not support any conclusions for the comparative efficacy between skeletal muscle relaxants for musculoskeletal conditions. Cyclobenzaprine had the largest body of evidence to support its efficacy compared to placebo. **Metaxalone was not more effective than placebo.***
- *The evidence does not support any conclusions for the comparative safety of any of the skeletal muscle relaxants in these conditions. **Chlorzoxazone is associated with rare serious dose-related hepatotoxicity.** The subcommittee notes that only carisoprodol and its active metabolite, meprobamate, are Schedule IV controlled substances in Oregon.*
- *The evidence does not support any conclusions about the comparative efficacy or adverse effects for different subpopulations of patients such as race, gender, or age.*

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Health Resources Commission

The State of Oregon's Health Resources Commission is a volunteer commission appointed by the Governor. The Health Resources Commission provides a public forum for discussion and development of consensus regarding significant emerging issues related to medical technology. Created by statute in 1991, it consists of four physicians experienced in health research and the evaluation of medical technologies and clinical outcomes; one representative of hospitals; one insurance industry representative; one business representative; one representative of labor organizations; one consumer representative; two pharmacists. All Health Resources Commissioners are selected with conflict of interest guidelines in mind. Any minor conflict of interest is disclosed.

The Commission is charged with conducting medical assessment of selected technologies, including prescription drugs. The commission may use advisory committees or subcommittees, the members to be appointed by the chairperson of the commission subject to approval by a majority of the commission. The appointees have the appropriate expertise to develop a medical technology assessment. Subcommittee meetings and deliberations are public, where public testimony is encouraged. Subcommittee recommendations are presented to the Health Resources Commission in a public forum. The Commission gives strong consideration to the recommendations of the advisory subcommittee meetings and public testimony in developing its final reports.