MEMO

DA: March 12, 1993

TO: Marc Desjardins
   Director, Management Services

FR: Marie Pellegrini, MSN, RN, C
   Manager, Occupational Health

RE: CORFLEX CRYOTHERM WRAP STUDY

Due to the concerted efforts of the staff at Notre Dame Center for Occupational Health, Occupational Therapy and Physical Therapy, we have successfully completed the Corflex Cryotherm Wrap pilot study. The results supported Cryotherm Wrap use, demonstrating excellent compliance rates, patient satisfaction with product use, and reported efforts of improved tolerance to work and other activities. The Cryotherm Wraps were reimbursed without any problems.

STUDY RESULTS:

Introduction
In cooperation with Marc Desjardins, Management Services, Notre Dame Center for Occupational Health (NDCON) implemented a trial study to assess the efficacy and feasibility of reimbursement of Cryotherm wraps, when used in the treatment of musculoskeletal sprains and strains of the injured worker.

Hypothesis
Our hypothesis was that the ease of use of the Cryotherm wrap in the treatment of musculoskeletal sprains and strains would increase patient compliance to frequent and regular application of cold and/or heat. This, in turn, would result in more comfort, earlier recovery from injury and sooner return to work.

Inclusion Criteria
Participants for the study were injured workers treated in NDCOH for a discrete musculoskeletal injury. In general, cold application was recommended for the acute sprain or strain or within 36-72 hours of initial trauma. Heat application was recommended for the subacute sprain or strain or for trauma over 72 hours from incident. The Cryotherm application was recommended for 20 minutes, 4-6x/day. Directions for Cryotherm wrap use, printed in several languages and supplied by the manufacturer, were reviewed and given to the patient.

Description Of The Sample
The population size was a total of 26 patients. This was 59% of the total 43 patients to whom Cryotherm wraps had been dispersed. Due to various reasons, including referral to outside providers, only 26 questionnaires were collected for analysis, although an effort was made to collect all questionnaires.

The injury distribution included lumbar strains (11/26), leg contusions and strains (7/26), cervical/shoulder strains (5/26), contused ribs (2/26), and lateral epicondylitis (1/26).

Time Frame
The study was conducted over two months, from November 20, 1992 to January 20, 1993. The amount of time from date to injury to initial evaluation at NSCOH ranged form 0 days to 4 months (the person with the lateral epicondylitis), most (19 or 73%) were seen within 5 days. The Cryotherm wrap was dispensed on the day of the initial evaluation. The questionnaires were completed on the premises at approximately 2/3 the course of the recovery period, which ranged from day 3 to day 30, averaging at day 11.2.
Compliance
All 26 patients indicated daily use of the Cryotherm wrap in the following frequency distribution: 12, or 46%-1-2x/day; or 34% - 3-4x/day; 4, or 15% - 4x/day and 1, or 3% - less than once per day.

Most (42%, or 11) reported use of the wrap for both cold and heat application. Thirty-four % (9) used the wrap for just cold application and 26% (7) used the wrap for just heat application. Responses indicated Cryotherm wrap use both before and after exercise, with cold being used slightly more frequently than heat.

Ease Of Use
When asked to compare with other forms of heat or cold application, 84% (22) reported the Cryotherm wrap as easier to use and 53% (14) indicated that the effect lasted longer. Only one person reported the effect as shorter and that the wrap was more difficult to use. This patient used a vari-wrap to treat chronic lateral epicondylitis, for which her initial evaluation was 4 months from onset of symptoms. She also identified difficulty applying it to her elbow without assistance.

Concomitant Treatment And Activity
Most respondents reported concurrently taking medication (67%, or 18), usually a non-steroidal anti-inflammatory medication. Over half of the population (57%, or 15) attended physical or occupational therapy, and slightly more (69%, or 18), including all therapy patients, reported exercising at home on an average of once to more than twice daily.

Results
Reported Effects
Participants overwhelmingly identified improved comfort and tolerance to activity with use of the Cryotherm wrap. They specifically reported the following effects:

<table>
<thead>
<tr>
<th>Effect</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Decreased pain</td>
<td>84% (22)</td>
</tr>
<tr>
<td>More comfort</td>
<td>81% (21)</td>
</tr>
<tr>
<td>Better sleep</td>
<td>57% (15)</td>
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<tr>
<td>Better tolerance to work</td>
<td>50% (13)</td>
</tr>
<tr>
<td>Better tolerance to exercise activity</td>
<td>50% (13)</td>
</tr>
<tr>
<td>Better tolerance to PT/OT</td>
<td>31% (8)</td>
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</tbody>
</table>

It is interesting to note that, although 50% of the respondents indicated better tolerance to work due to the Cryotherm wrap, only one person (3%) actually used the Cryotherm wrap at work.

Satisfaction With Care
In general, 92%, or 24 indicated that they were “very pleased” with the care received at the Notre Dame Center for Occupational Health. Two other respondents (7%) reported that they were “pleased.” They had a lumbar strain and chronic lateral epicondylitis, and rated their pain level at 8/10 and 6/10 respectively at that time. This was twice the average pain level reported by all other participants, whose average was 3.2, and may have played a role in level of satisfaction.

Summary And Conclusion
In summary, this pilot study supported the use of the Cryotherm wrap as one component in the management of acute musculoskeletal sprains and strains of the injured worker. Participants demonstrated excellent compliance with both cold and heat application, with 59% using the wrap at least 3x/day and 100% using them at least once daily.

When asked to compare with other conventional forms of cold or heat application, the Cryotherm wrap was rated as easier to use by 88%, and as having longer lasting effects by 53%.

We conclude that the ease of application, as well as the ease of switching from use of cold to heat, using the same Cryotherm wrap, has greatly contributed to this high compliance rate.
We acknowledge that this was an uncontrolled study population, influenced by the perception of the individual participating. However, perception of wellness and a sense of control over one’s body or symptoms correlates directly with willingness to participate in one’s care. The respondents in this study reported that the Cryotherm wrap application resulted in the effects of decreased pain (88%), improved comfort (83%), and improved tolerance of work (50%), exercise (50%) and improved sleep (50%).

We believe that increased participation in the above activity and other components of one’s treatment program results in earlier return to work and earlier return to full duty.

This study also demonstrated that Cryotherm wrap reimbursement for the injured worker is not a problem. Payments have been received (as noted on Appendix A) and there has been no payment refusal or dispute by insurance carriers or self-insured companies.

In conclusion, we feel justified in adding the Cryotherm wrap to our armamentarium for use in the managed care of the injured worker. This study demonstrated ability for reimbursement and acceptance by the patient, with reported effects of improved tolerance to work, exercise and other activity.

The Corflex Cryotherm wrap specifically contributes to the management of the injured worker, due to: ease of applicability and reuse; and ease of switching from cold to heat, thereby being economical and very useful to the patient.

Addendum: The above article will be submitted for publication to various nursing and occupational health journals.

Appendix A

Reimbursement – Cryotherm Wraps
Date of Dispensing: 11/20/92 – 2/20/93
Total Wraps Dispensed: 47
Total Reimbursed (as of 3/12/93): 21
Total Rejected: 0
Total Waiting for Payment: 26