



COMMUNITY HEALTH PLAN
of Washington

Committed to your health.

Section 3: Prior Authorization Criteria 2007

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Medical Guidelines Overview

Purpose. The attached evidenced-based medical guidelines were developed to assist centers and affiliates of Community Health Network in the treatment of Community Health Plan members.

Contents. This publication contains routine care and screening, disease management, and prior authorization criteria. These guidelines have been reviewed by network representatives and medical directors and are applicable to the centers and affiliates making up the Community Health Network.

Changes to Guidelines. Requests for changes or additions to the attached guidelines are encouraged and should be addressed to:

Medical Director
Community Health Plan
720 Olive Way, Suite 300
Seattle, WA 98101

A change request form starts at page ii.

Requests for additions or changes will be reviewed and forwarded with recommendations by the Community Health Plan Medical Director and/or Chief Medical Officer to the Medical Director Roundtable for review. Originators of requests will be provided a copy of the recommendations and of the final action.

New Technology and Medical Device Coverage Requests. Community Health Plan strives to provide our members with quality health care utilizing proven technological and medical device advancements. The attached New Technology and Medical Device Coverage Request Form starting at page iv may be completed and forwarded to the Community Health Plan's Medical Director for recommendation and determination by the Medical Director Roundtable.

Published. Community Health Plan's Medical Guidelines are published annually in the month of January. Changes are made as needed and are posted on the CHP website. Hardcopies are available by request by calling the CHP Medical Management department.

Reprint Authority. The attached medical guidelines may be reprinted in part or in their entirety by member centers or affiliates of Community Health Network for the specific purpose of treatment of Community Health Plan members.

Request for New Addition or Change to Existing Medical Guideline

REQUEST FOR NEW ADDITION OR CHANGE TO EXISTING MEDICAL GUIDELINE		
Originated: 12/02		
Please complete blocks 1-24 and forward with any attachments to the Medical Director, Community Health Plan, 720 Olive Way, Suite 300, Seattle, WA 98101 or fax to (206) 521-8834 attn: Medical Director. Upon completion of review by the Medical Director, your request will be forwarded to the CHP Utilization Subcommittee for determination.		
1. Date of Request:	2. Requesting Individual's Name:	
3. Name of Organization:	4. Individual's Title:	
5. Organization Address:		
City: State: Zip Code:		
6. Phone: ()	7. Fax: ()	8. Email:
9. Type of action requested: <input type="checkbox"/> New guideline <input type="checkbox"/> Change to existing guideline	10. Subject of guideline:	
11. Specific guideline change or addition requested:		
12. Identify published, peer-reviewed literature which documents the efficacy and/or clinical effectiveness for the guideline requested. (Please attach articles or provide a bibliography.)		

13. How would the patient benefit from this requested change in the guideline? Would quality of care be improved?		
14. Is this guideline change cost-effective in comparison to other treatments currently available?		
15. Are there any additional advantages to the patient or Plan for using this guideline?		
15. Do you know if any relevant medical associations (e.g., AMA, ACOG, etc.) have expressed an opinion about this information/treatment in this requested guideline change? If so, what is that opinion?		
16. Do you know if any medical review organizations (e.g., Hayes, Cochran, etc.) have expressed an opinion about this guideline/procedure? If so, what is that opinion?		
For CHP Use Only	Date Received:	CHP Reviewer:
CHP Medical Director Forwarding Endorsement To: _____ The above requested change to CHP Medical Guidelines has been carefully reviewed and is <input type="checkbox"/> recommended, <input type="checkbox"/> recommended for limited or trial use, <input type="checkbox"/> or not recommended for approval based on the following information (attach additional information as required). _____ / _____ CHP Medical Director Date		Date:
Committee Determination After reviewing the request, the committee has taken the following action: <input type="checkbox"/> Approved the request as submitted. <input type="checkbox"/> Approved the request with the following limitations and/or trial period requirements. (See remarks.) <input type="checkbox"/> Disapproved the request for the following reasons. (See remarks.) Remarks: _____ / _____ Chairperson Date <input type="checkbox"/> Notification letter sent to request originator.		Date:

New Technology and Medical Device Coverage Request Form

New Technology and Medical Device Coverage Request Form

Revised: 12/02

Please complete blocks 1-24 and forward with any attachments to the Medical Director, Community Health Plan, 720 Olive Way, Suite 300, Seattle, WA 98101 or fax to (206) 521-8834 attn: Medical Director. Upon completion of review by the Medical Director, your request will be forwarded to the CHP Utilization Subcommittee for determination.

1. Date of Request:		2. Requesting Individual's Name:	
3. Name of Organization:		4. Individual's Title:	
5. Organization Address: City: State: Zip Code:			
6. Phone: ()		7. Fax: ()	8. Email:
9. Name of Device:		10. Manufacturer of Device:	
11. Purpose/use of Device: (Please attach additional sheets as desired.)			
12. Identify published, peer-reviewed literature which documents the efficacy and/or clinical effectiveness of this device. (Please attach articles or provide a bibliography.)			
13. Is the device FDA approved? <input type="checkbox"/> Yes <input type="checkbox"/> No		14. If yes, when was it approved by the FDA?	
15. If yes, for what indication or use was it approved?			
16. How does this device differ from other devices currently on the market for the same indication? How is it more efficacious?			
17. How is this device more efficacious than medical treatment for the same indication?			
18. What is the total cost for the device? Are there any ongoing costs associated with using the device? If so, what?			

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Committee Determination

Date:

After reviewing the request, the Committee has taken the following action:

- Approved the request as submitted.
- Approved the request with the following limitations and/or trial period requirements (see remarks).
- Disapproved the request for the following reasons. (See remarks.)

Remarks:

_____/_____
CHP Medical Director Date

Notification letter sent to request originator.

Quick Glance

The following grid provides a **QUICK GLANCE** look at **ALL** services that require Prior Authorization by the CHP and the corresponding criterion used for medical review. **C** = CHP criteria **M** = Milliman Ambulatory Care Guidelines (unless otherwise specified).

Service/Item	Clinical Criteria	Remarks
Acupuncture	C	See Alternative Care Guideline
Apnea Monitors	C	
Biofeedback Therapy	C	See Alternative Care Guideline
Bladder Neck Suspension	M	
Blepharoplasty	M	
Botox™ Injections	M	
Breast Reduction Mammoplasty	M	
Bunionectomy	M	
Cardiac Rehabilitation	M	
Chiropractic Care	M	
Cochlear Implants	M	
Communication Devices	C	Refer to CHP DME Formulary
Continuous Passive Motion Machine	C	
C-Pap/Bi-Pap Machines	C	
Dental Services	C	
Dialysis (Kidney)	C	CHP Case Manager Referral Required
Enbrel™ (etanercept)	M	
Growth Hormone Therapy	M	
Hip Replacement Surgery	M	
Home Health Care	M	
Home Infusion Therapy	M	
Hospice Care	C	CHP Case Manager Referral Required
Hospital Beds & Accessories	M	Also refer to CHP DME Formulary
Hyperbaric Oxygen Pressurization	M	
Hypnotherapy	C	See Alternative Care Guideline
Insulin Pumps	M	
Knee Replacement Surgery	M	
Massage Therapy	C	See Alternative Care Guideline
Medical Nutritional Therapy	C	

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Service/Item	Clinical Criteria	Remarks
MRI/MRA	M	
Naturopathy	C	See Alternative Care Guideline
Occupational Therapy	M	
Orencia™ (abatacept)	C	
Orthotics	C	Refer to CHP DME Formulary
Osteogenic Bone Stimulators	M	
Oxygen & Supplies	M	
Patient Lifts	C	Refer to CHP DME Formulary
PET Scans	M	
Physical Therapy	M	
Prosthetic Limbs	C	Refer to CHP DME Formulary
Reconstructive Plastic Surgery	M	
Rehabilitation (Inpatient)	C	CHP Case Manager Referral Required.
Remicade™ (infliximab)	C	
Rituxan™ (rituximab)	C	
Skilled Nursing Facility	C	See Rehabilitation (Inpatient) guideline CHP Case Manager Referral Required.
Speech Therapy	M (adult) C (peds)	
Suction Pumps	C	
Synagis™/RespiGam™	M	
TENS Unit	M	
TMJ/MPD Treatment	C	
Transmyocardial Laser Revascularization	M	
Transplants, Bone Marrow	C	Interlink 2005 - 2006
Transplant Donor Search (tissue typing) / Donation	C	Interlink 2005 - 2006
Transplant Work-ups	C	Interlink 2005 - 2006
Transplants, Solid Organ (excluding corneal)	C	Interlink 2005 - 2006
Tysabri™ (natalizumab)	C	
Uvulopalatopharyngoplasty	M	
Ventilators	M	CHP Case Manager Referral Required
Viscosupplementation (Synvisc™/Hyalgan™, etc.)	C	
Wheelchairs	M	
Wound Care	M	
Xolair™ (omalizumab)	M	

NOTE: All services are subject to eligibility, benefit limitations and exclusions. Please refer to your 2007 Benefit Grids for more specific information.

To obtain a copy of criteria:

- Community Health Plan guidelines may be obtained from Community Health Plan's web site (chpw.org). A copy of an individual criteria set may be obtained from the web-site, or by calling Community Health Plan customer service (800-440-1561).
- Milliman Care Guidelines are proprietary, and at this time, only Member CHC's have direct access; affiliate clinics and specialist providers may obtain Milliman criteria on a case-by-case basis. To obtain a copy of a specific Milliman guideline, telephone Customer Service (800-440-1561), or email guidelinerequests@chpw.org. When requesting a guideline, please include your name and telephone number so UM staff can call and discuss your request.

For Medicare Advantage, CHP uses CMS National Coverage Determinations.

- CMS National Coverage Determinations may be found on the CMS website: <http://www.cms.hhs.gov> under the Medicare Coverage Database section.

1 *Alternative Care*

Subject: Alternative Care (Acupuncture, Biofeedback, Chiropractic, Hypnotherapy, Massage Therapy, Naturopathy)	
<input type="checkbox"/> Original <input checked="" type="checkbox"/> Revised	Original Committee Approval: November 5, 1997 Last Committee Approval: December 20, 2006 Last Review: October 2006

This CHP guideline is used for all Alternative Care except Chiropractic. For Chiropractic, the annotations here are used in conjunction with Milliman Care Guidelines.

1. Background:

The “Every Category of Provider Rule”, as it is referred to, is addressed in RCW 48.43.045(1)(a)(b) and reads as follows:

Every health plan delivered, issued for delivery or renewed by a health carrier on and after January 1, 1996, shall:

Permit every category of health care provider to provide health services or care for conditions included in the basic health plan services to the extent that:

1. The provision of such health services or care is within the health care providers’ permitted scope of practice; and
2. The providers agree to abide by standards related to:
 - a) Provision, utilization review, and cost containment of health services,
 - b) Management and administrative procedures, and
 - c) Provision of cost-effective and clinically efficacious health services.

It is the intent of the ruling that if a condition is covered by the Plan, any category of provider who meets the requirements of the rule may provide treatment for the covered condition.

2. Required Review and Approvals:

Alternative Care requires prior authorization by the CHP Medical Director or his/her designee.

3. Requests for Continuation of Treatment:

When reviewing a case where there is a request for ongoing therapy, all of the following must be documented:

- The referring provider is requesting additional therapy,

- An initial intake evaluation with the practitioner occurred and a defined set of measurable treatment goals was established *before* therapy was initiated, and these goals are deemed reasonable and appropriate for the condition being treated,
- The patient has been compliant with the treatment,
- The patient has made consistent gains toward meeting the initial treatment goals,
- The practitioner has defined a self-management program for the patient, and there is evidence that the patient is progressing towards independence with this program, and
- The practitioner defines the expected number of additional visits likely necessary to achieve the treatment goals.

4. Limitations/Exclusions:

Healthy Options:	Not covered.
PEBB:	None.
Basic Health Plan:	None.
GAU:	Not covered.
Medicare Advantage:	Not covered except Chiropractic and MA-Urban limited acupuncture benefit

ACUPUNCTURE

Acupuncture is based on the principles of traditional Chinese medicine, which are founded on the notion of “qi”, or energy circuits throughout the body. Imbalances in the flow of “qi”, which follows fourteen major pathways (“meridians”) in the body, create disease. By inserting special needles at specific points along the meridians, acupuncture tries to rebalance “qi”, thereby promoting healing. Needling is commonly combined with heat or electricity.

1. Required Referral Criteria:

- Symptoms must have been present for more than 3 months.
- Member must have been seen by the PCP within the 3 months prior to the referral request.
- A maximum of **8 visits over a 4-month period** may be approved.
- Feedback must be given to the PCP regarding the patient’s progress and status.

2. Covered Conditions:

- Chronic myofascial pain (including cervicalgia, chronic neck and back pain, lumbago, muscular tension headaches, plantar fasciitis, and tendonitis)

- Fibromyalgia (requires an established, documented diagnosis of fibromyalgia consistent with the 1990 American College of Rheumatology Criteria)
- Chronic arthritis
- Chronic headaches, including adult and pediatric migraine, and muscle tension
- Pain secondary to metastatic disease
- Chronic neuropathic pain
- Chemotherapy nausea and vomiting (may approve 1 visit each week the patient receives chemotherapy)
- Post-operative nausea and vomiting
- TMJ disorders (**note: BHP does not cover treatment of TMJ.)
- Dysmenorrhea
- Hyperemesis of pregnancy (condition does not have to be present for more than 3 months; may approve 1 visit/week for up to 8 weeks)

3. References:

- Hayes Inc. Online 2006.
- Milliman Care guidelines 2006.
- Aetna. Acupuncture. Aetna Clinical Policies 2006 Mar 31;(Bulletin #0135).
- Summary #23: Acupuncture. [Online]. 2003. Available From URL:www.guideline.gov.
- NIH Consensus Statement 1997.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

BIOFEEDBACK

A training program designed to develop one's ability to control the automatic nervous system. Proponents state that a patient can learn to control their heart rate, blood pressure and skin temperature to relax certain muscles.

1. Required Referral Criteria:

- Symptoms must have been present for more than 3 months.
- Member must have been seen by the PCP within the 3 months prior to the referral request.
- A maximum of **8 visits over a 4-month period** may be approved.
- Feedback must be given to the PCP regarding the patient's progress and status.

2. Covered Conditions:

- Pediatric migraine or tension headache
- Generalized anxiety disorder
- Urinary incontinence

3. References:

- Hayes Inc. Online 2006.
- Premera Blue Cross. Corporate medical policy. [Online]. 2006 Sep. Available from URL:<http://www.premera.com>.
- Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: Evidence-based guidelines for migraine headache. *Neurology* Sep 26;55(6):754-62.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

CHIROPRACTIC CARE:

See Milliman "Chiropractic Care" guideline.

Exclusion Criteria listed below override the Milliman coverage criteria.

- a. Children younger than 16 years of age
- b. Evidence of concomitant neurologic deficit or radiculopathy is present
- c. Preventive therapy
- d. Maintenance therapy

NOTE: PEBB members may self refer for manipulation of spine and extremities (chiropractic care), up to 12 visits per year. Prior authorization by the CHP is required if >12/year).

HYPNOTHERAPY

A treatment intervention aimed at inducing an altered state of awareness whereby the patient's objective manifestations of the mind are inactive and accompanied by an increased susceptibility to suggestions.

1. Required Referral Criteria:

- Symptoms must have been present for more than 3 months.
- Member must have been seen by the PCP within the 3 months prior to the referral request.

- A maximum of **8 visits over a 4-month period** may be approved. Feedback must be given to the PCP regarding the patient's progress and status.

2. Covered Conditions:

- Chronic pain,
- Cancer pain,
- Post-operative pain, and
- Anxiety disorders, somatization disorders, sleep disorders and dissociative disorders.

3. References:

- Premera Corp. Med. Policy 2006 Aug 8;(#2.01.508).
- NIH Technology Assessment Conference Statement. Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia; 1995 Oct 16-18:1-34.
- Veteran's Health Administration. Clinical practice guidelines for the management of post-operative pain. National Guidelines Clearinghouse; 2002 May.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

MASSAGE THERAPY:

A treatment involving manipulation, methodical pressure, friction and kneading of the body.

1. Required Referral Criteria:

- Symptoms must have been present for more than 3 months.
- Member must have been seen by the PCP within the 3 months prior to the referral request.
- A maximum of 8 visits over a 4-month period may be approved. Feedback must be given to the PCP regarding the patient's progress and status.

2. Covered Conditions:

- Subacute (between 2-6 months in duration) myofascial pain is covered including:
 - i. Tendonitis,
 - ii. Plantar fasciitis,
 - iii. Epicondylitis (tennis elbow),

- iv. Thoracic outlet syndrome, and
- v. Neck and back strain.
- Acute myofascial pain (less than 2 months duration) and chronic myofascial pain (more than 6 months duration) are not covered.
- Fibromyalgia is not covered.
- **NOT** covered for relaxation or other indications.

3. References:

- Cherkin DC, et al. Randomized trial comparing traditional Chinese acupuncture, therapeutic massage, and self-care education for chronic low back pain. Arch Intern Med 2001;161:1081-8 (from Hayes Inc. Online).
- Aetna Clinical Policies Bulletin #0325 (revised 4/07/06). Physical Therapy Services.
- Premera Corp. Medical Policy #8.03.02 (revised 5/13/06). Physical Therapy.
- 2006 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

NATUROPATHY

Naturopathy is a system of healing that is founded on the basic premise that the body has an inherent capacity to establish, maintain, and restore health. It focuses on the healing power of nature, in the form of nutritional supplements, medicinal plants, and on both physical and spiritual exercises to promote the treatment of the whole individual.

1. Required Referral Criteria:

- Symptoms must have been present for more than 3 months.
- Member must have been seen by the PCP within the 3 months prior to the referral request.
- A maximum of **3 visits over a 4-month period** may be approved. Feedback must be given to the PCP regarding the patient's progress and status.

2. Covered Conditions:

- Chronic fatigue.
- Chronic arthritis
- Chronic irritable bowel syndrome.
- Fibromyalgia (The patient must have an established, documented diagnosis consistent with the 1990 American College of Rheumatology Criteria.)
- Chronic sinusitis (unresponsive to conventional medical treatment).

- Chronic serous otitis media (defined as persistent middle ear fluid for more than 3 months).
- Premenstrual syndrome.
- Menopausal symptoms (excludes symptoms of excessive bleeding).
- Headaches (persistent migraine, tension-type, or sinus-related).
- Atopic dermatitis/chronic eczema.
- Asthma (mild to moderate), if treatment is not dependent on oral steroids.

3. References:

- Saxton, J, Director of Library Services. Personal communication. Bastyr University, 2004 Nov 29.
- NCCAM (NIH). Whole Medical System: An Overview. [Online]. 2004 [cited 2007 Jan 26]. Available from URL:<http://nccam.nih.gov/health/backgrounds/wholemed.htm>
- Soeken KC. Selected reviews of complementary and alternative medicine therapies for arthritis-related pain: the evidence from systematic reviews. Clin. J. Pain 2004 Jan-Feb;20(1):13-8.
- Sarrell EM, et al. Naturopathic treatment for ear pain in children. Pediatrics 2003 May;111:574-9.
- NCAHF. National Council Against Health Fraud. [Online]. 1999 [cited 2007 Jan 26]. Available from URL:www.ncahf.org.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

2 Apnea Monitors

Subject: Apnea Monitors (Home) for Infants

<input type="checkbox"/> Original	Original Committee Approval: January 1, 2002
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
Last Review: October 2006	

1. Background:

Apnea is the cessation of respiratory airflow. Apnea may be central (no effort to breathe), obstructive (trying to breathe, but unable to ventilate due to airway obstruction), or mixed (some elements of central and obstructive). It is not uncommon for premature infants to have apnea of undetermined etiology.

2. Indications/Criteria:

Before considering placing an infant on a home apnea monitor, the infant must have been thoroughly evaluated to be certain there is no specific, treatable reason for the apnea. If no treatable etiology is found, a home apnea monitor may be medically necessary for infants who meet ANY of the following criteria:

- Born < 37 weeks gestation, and the infant is not more than 43 weeks corrected gestational age,
- Had an apparent life-threatening apneic event (defined as requiring mouth-to-mouth resuscitation or vigorous stimulation),
- Has been diagnosed with bradycardia and is being treated with caffeine, theophylline, or other stimulating agents,
- Has documented gastro-esophageal reflux which results in apnea, bradycardia, or oxygen desaturation,
- Has documented apnea greater than 20 seconds in duration,
- Has apnea for periods less than 20 seconds in duration and accompanied by bradycardia, cyanosis, or pallor,
- Has bradycardia (defined as heart rate < 100 beats per minute),
- Has oxygen desaturation below 90%, or
- Has neurologic / anatomic / metabolic or respiratory diseases affecting respiratory drive.

Monitoring may continue until the infant has gone 6 weeks without an apneic or bradycardic event.

Additionally, apnea monitors may be approved for patients diagnosed with pertussis. Coverage will be for one month after the diagnosis is made.

3. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	DME benefit limit of \$500 / calendar year
GAU:	None; pre-authorization required
Medicare Advantage:	None; pre-authorization required.

4. Required Review and Approvals:

Home apnea monitors require prior authorization by the CHP Medical Director or his/her designee.

5. References:

- Aetna. Apnea Monitors for Infants. Aetna Coverage Policy 2006 Feb 7;(Bulletin #0003). [Online]. Available from URL:www.aetna.com.
- Premera. Home Apnea Monitoring. Premera Corporate Medical Policy 2005 Oct 11;(1.01.511). [Online]. Available from URL:www.premera.com.
- National Heart, Lung, and Blood Institute. Breathing Problems During Sleep May Affect Mental Development in Infants and Young Children. NIH News Bulletin 2004 Oct 7.
- American Academy of Pediatrics National Guidelines, 2003: Apnea, sudden infant death syndrome, and home monitoring. Pediatrics 2003 Apr;111:914-7.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

3 Blepharoplasty

Subject: Blepharoplasty	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

Clinical guidelines changed from CHP Criteria to Milliman CareGuidelines.

4 Continuous Passive Motion Machine

Subject: Continuous Passive Motion Machine (CPM)	
<input type="checkbox"/> Original <input checked="" type="checkbox"/> Revised	Original Committee Approval: December 15, 2004 Last Committee Approval: December 20, 2006 Last Review: October 2006

1. Background:

Passive motion involves movement of a joint without active contraction of muscle groups. It is used to maintain range of motion and flexibility in joints in the early postoperative and rehabilitative period after surgery or injury. Active movements during this period might disrupt the repair process or may be too painful to perform. Continuous Passive Motion (CPM) devices permit passive movements to be done when a patient is sleeping, for long periods of time as indicated, or when there is no caregiver available to perform physical therapy.

2. Indications/Criteria:

CPM will serve as an adjunct to both active and passive physical therapy modalities in the immediate post-operative setting to improve range of motion, reduce swelling and pain, and promote cartilage regeneration. CPM must be started within 2 days post-op and will not be covered for more than 10 days. It can be employed in the home setting. It should complement an active physical therapy program.

3. Covered Conditions:

- Total Knee Arthroplasty.
- Shoulder, elbow, hand (i.e., upper extremity) surgical releases for arthrofibrosis or adhesive capsulitis.
- Rotator-cuff injuries/repair.
- Arthroplasty of shoulder and elbow.
- Intra-articular cartilage fracture repair/ chondroplasty (e.g., tibial plateau fracture).
- Dupuytren's contracture.
- ACL repair.

4. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	DME benefit limit of \$500 / calendar year
GAU:	None; pre-authorization required
Medicare Advantage:	None; pre-authorization required (use CMS NCD's)

5. References:

- Hayes Inc. Online 2006.
- Milliman 2006.
- Aetna. Continuous Passive Motion. Aetna Clinical Practice 2006 Apr 21 ;(Bulletin #0010).
- CMS Coverage Issues Manual (DME) 2006.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

5 Continuous Positive Airway Pressure

Subject: Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airway Pressure (BiPAP)

<input type="checkbox"/> Original	Original Committee Approval: December 10, 1998
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
Last Review: October 2006	

****Note:** Prior Authorization criteria apply only to the purchase of CPAP or BiPAP equipment. Effective in 2007, rental of equipment does not require prior authorization.

1. Background

CPAP is a non-invasive technique for providing low levels of positive airway pressure from a flow generator through the nostrils via a nose mask. This pressure is delivered each time the patient inhales. BiPAP is similar, but adds the ability to deliver positive airway pressure during the exhalation phase of breathing. There are generally two recognized conditions for which CPAP may be considered medically necessary:

- Obstructive Sleep Apnea Syndrome (OSAS).
- Upper Airway Resistance Syndrome (UARS).

The CPAP device treats OSAS and UARS by preventing the collapse of the oropharyngeal walls. It is the collapse of these soft tissues that leads to obstruction of airflow during sleep. In patients with OSAS or UARS, CPAP therapy may improve symptoms such as excessive daytime sleepiness and improve some measures of cognition and psychological well-being. In patients with moderate to severe OSAS there is evidence of increased mortality, but there remains insufficient evidence that treatment with CPAP reduces mortality in these patients.

BiPAP may be used in patients with OSAS if treatment failure has been documented with CPAP therapy.

2. Indications:

OSAS is divided into three categories of severity:

- Mild OSAS: the apnea-hypopnea index (AHI)* is greater than five and less than 20.
- Moderate OSAS: the AHI is 20 to less than 50.
- Severe OSAS: the AHI is 50 or greater.

*The apnea-hypopnea index (AHI) is defined as follows:

Apnea is the cessation of airflow for 10 or more seconds. Hypopnea is a temporary reduction of airflow accompanied by a 2% or greater drop in oxygen saturation. The AHI is the average hourly rate of combined apnea and hypopnea events documented during the course of any polysomnography during which a minimum of two hours of sleep are recorded.

UARS patients have a normal AHI (five or less), but have demonstrated sleep fragmentation due to subtle airway resistance. Such resistance leads to repetitive arousals and prevention of restorative sleep. The Respiratory Arousal Index (RAI) measures the frequency of such arousals.

The following criteria apply:

1. Polysomnography monitoring demonstrates an AHI of greater than 15.
- OR**
2. Polysomnography monitoring demonstrates an AHI of greater than five with at least one of the following symptoms/clinical conditions:
 - a) excessive daytime sleepiness documented by either Epworth Sleepiness Scale score >10 or Multiple Sleep Latency Test < 6,
 - b) mood disorder,
 - c) impaired cognition,
 - d) documented hypertension, ischemic heart disease or history of stroke, and/or
 - e) 20 episodes of desaturation to < 85% OR one episode to < 70% during a full night study.
- OR**
3. A diagnosis of UARS is established by a sleep study showing all of the following:
 - a) An AHI equal to or less than 15,
 - b) A RAI of greater than or equal to 20, and
 - c) An Epworth Sleepiness Scale score greater than 10 or Multiple Sleep Latency Test less than six.

3. Limitations/Exclusions:

Healthy Options:	None.
PEBB:	None.
Basic Health Plan:	DME benefit limit of \$500 / calendar year
GAU:	None.
Medicare Advantage:	None. Use CMS NCDs

****Additional Requirements for Purchase of CPAP or BiPAP:**

- Trial of rental equipment for a minimum of two (2) months,
- Documentation of clinical response, and
- Documentation of patient tolerance and compliance with use of equipment.
- CPAP or BiPAP purchase must be authorized by the Plan Medical Director or her/his designee.

4. Required Review and Approvals:

CPAP or BiPAP purchase requires prior authorization by the Plan Medical Director or her/his designee.

5. References:

- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.
- Aetna. Obstructive sleep apnea. Aetna Clinical Practice 2006 Jul 14;(Bulletin #0004).
- Premera. Obstructive sleep apnea. Premera Corporate Medical Policy 2006 May 9;(#2.01.503)
- 1998 HCPCS Coverage Issues Manual.
- Centers for Medicare and Medicaid Services. Medicare Coverage Database: NCD for CPAP (240.4); publication no. 100-3; manual section no. 240.4; effective date of version: 2005 Apr 4.
- National Guideline Clearinghouse. Diagnosis and treatment of obstructive sleep apnea. [Online]. 2004 Jan 28. Available from URL:www.guideline.gov.
- Evidence-based medicine. J Respir Crit Care Med 1999 Feb;159:461-7.
- Johns MW. A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. Sleep 1991;14(6):540-5.

6 Dental Services

Subject: Dental Services	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

1. Background:

Routine dental services are not covered by CHP for any line of business. However, each program includes coverage of dental services required for underlying medical conditions and, in some cases, there is an accidental dental benefit.

2. Covered Dental Services:

1. Underlying medical conditions

Services performed by dental providers (dentist, oral surgeon) for underlying medical conditions. For example: Excision of tumors or cysts of the jaw, cheeks, lips, tongue, gums, roof and floor of the mouth; incision of salivary glands and ducts; extraction of teeth associated with radiation therapy, chemotherapy, or organ transplantation; reduction of a fracture or dislocation of the jaw or facial bones.

For TMJ/MPD coverage and authorization requirements see CHP Guideline "Temporomandibular Joint Dysfunction (TMJ)".

2. Dental Anesthesia (coverage includes anesthesia costs and facility fees)

BH: When procedure cannot be performed in dental office due to member's underlying condition or clinical status.

HO: Dental anesthesia services are covered by DSHS.

PEBB: General anesthesia services and related facility charges in conjunction with any dental procedure performed in an ambulatory surgical center are covered if such anesthesia services and related facility charges are medically necessary because the enrollee:

1. Is under the age of seven, or physically or developmentally disabled, with a dental condition that cannot be safely and effectively treated in a dental office; or
2. Has a medical condition that the enrollee's physician determines would place the enrollee at undue risk if the dental procedure were performed in a dental office. The procedure must be approved by the enrollee's physician.

- GAU:** Some dental services are covered by DSHS. If covered, all facility-based services are paid by DSHS.
- MA:** When procedure cannot be performed in dental office due to member's underlying condition or clinical status.

3. Accidental Dental

- BH:** Dental services intended to repair an accidental injury to sound natural teeth or jaw. Treatment must begin within 90 days of the injury or as soon as medically feasible. Services performed must be directed toward repair of functional disorder (resulting from injury) rather than cosmetic restoration.
- HO:** Accidental dental services are covered by DSHS.
- PEBB:** Repair of accidental injury to natural teeth, excluding orthodontic care and dental implants. Evaluation of the injury and development of a written treatment plan must be completed within 30 days from the date of injury. Treatment must be completed within the time frame established in the treatment plan unless delay is medically indicated and the written treatment plan is modified.
- GAU:** Some dental services are covered by DSHS. If covered, all facility-based services are paid by DSHS.
- MA:** As determined to be medically necessary by the Plan (according to CMS NCD).

3. Limitations / Exclusions:

General:	Dental services related to TMJ unless pre-approved by the Plan Oral surgery, including jaw adjustments to correct malocclusion Treatment of gum disease Tooth extractions Orthodontia Surgery to accommodate dentures Orthognathic surgery (upper/lower jaw augmentation or reduction) Dental splints or guards Dental implants Restorative dentistry not due to accidental injury
Basic Health Plan:	Routine dental care is not a covered benefit.
Healthy Options:	Not covered by plan but covered by DSHS.

PEBB:	Orthognathic surgery; surgical treatment (upper and lower jaw augmentation or reduction services) of temporomandibular joint dysfunction (TMJ) or myofascial pain dysfunction (MPD); injuries caused by biting or chewing; malocclusion resulting from an accidental injury; conditions not directly resulting from the accident; and treatment not completed within the time period established in the written treatment plan.
GAU:	Some dental services are covered by DSHS.
Medicare Advantage:	Dental surgeries or treatments are not covered

4. Required Review and Approvals:

Prior Authorization is required for dental anesthesia and accidental dental services (if covered). Prior Authorization is required for dental extractions required before treatment of head/neck cancer. Authorization by the CHP Medical Director or his/her designee.

5. References:

- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

7 Dialysis (Kidney)

Subject: Dialysis (Kidney)	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

This service requires a referral to Community Health Plan's Case Management Department.

1. References:

CHP Case Management ESRD desk procedure,

8 Enbrel™ (Etanercept) Injections

Subject: Enbrel™ (Etanercept) Injections	
<input type="checkbox"/> Original	Original Committee Approval: December 8, 2004
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: December 2006

2. Background:

Etanercept (Enbrel) Is A Self-Injectable Drug:

Self-injectable drugs, subject to various pharmacy benefit restrictions, will be covered by the pharmacy benefit unless the patient has conditions that prohibit him/her from self-administration of the medication. These conditions include but are not limited to:

- a) The member and family are physically unable to perform administration and adaptive equipment is not available, and
- b) The member and/or family lacks the cognitive ability to manage self-injection, recognize side effects, or understand when to notify their provider if problems occur.

Tumor necrosis factor-alpha (TNF- α) is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Etanercept (Enbrel®) binds specifically to tumor necrosis factor (TNF) and blocks its interaction with cell surface TNF receptors, rendering TNF biologically inactive and reducing the inflammation associated with rheumatoid arthritis (RA), and psoriatic arthritis.

3. Indications/Criteria:

In ALL cases, the patient must meet ALL of the following criteria:

- Four years old or older, and
- No evidence of sepsis, active infection including tuberculosis, or pancytopenia.

1. Active Ankylosing Spondylitis:
No other requirements.

2. Rheumatoid Arthritis, Juvenile Rheumatoid Arthritis, Psoriatic Arthritis:

At least one of the following criteria must be met:

- The patient has tried methotrexate (MTX), up to 25 mg per week, for at least 6 to 12 weeks and failed the treatment as defined by the following:
- No decrease in number of swollen or painful joints,
- No decrease in pain or disability,

- No improvement in global assessment that includes patient activity/functional assessment, OR
- Radiographic evidence of disease progression.

OR

- The patient did not tolerate methotrexate due to documented side effects such as stomatitis, severe diarrhea, increase in liver enzymes, new onset of significant lung disease, leucopenia, thrombocytopenia, vasculitis, hemorrhage or blurred vision.

OR

- Methotrexate is contraindicated for the patient (pre-existing liver disease, renal impairment, significant lung disease, alcohol abuse, pregnancy).

Recommended Dose:

The recommended dose for patients older than 17 years old is 25 mg subcutaneous injection twice a week or 50 mg subcutaneous injection once a week.

The recommended dose for patients 4-17 years old is 0.8 mg/kg subcutaneous injection once a week with a maximum recommended dose of 50 mg.

3. Plaque Psoriasis:

There must be documentation that the patient has undergone adequate trials of more conservative therapy and has failed to respond. Such conservative trials must include all of the following:

- Vitamin D analogues,
- Topical steroids, and
- Coal tar,

AND

There must be documentation that the patient has tried and failed phototherapy (UVB, PUVA) or has a contraindication to such therapy,

AND

There must be documentation that the patient has tried and failed systemic treatments including all of the following:

- Cyclosporine,
- Methotrexate, and
- Oral retinoids.

4. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required
PEBB:	None; pre-authorization required
Basic Health Plan:	None; pre-authorization required
GAU:	None; pre-authorization required
Medicare Advantage:	None; pre-authorization required

5. Required Review and Approvals:

Etanercept (Enbrel®) injections require prior authorization by the CHP Medical Director or his/her designee.

6. References:

1. American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the Management of Rheumatoid Arthritis: 2002 Update. *Arthritis Rheum* 2002;46:328-46.
2. Furst DE, et al. Updated consensus statement on biological agents for the treatment of rheumatoid arthritis and other rheumatic diseases. *Ann Rheum Dis* 2002 May;61(Suppl 2):ii2-ii7.
3. Immunex Corporation. Enbrel® (etanercept) prescribing information. Thousand Oaks (CA): Immunex Corporation; 2003 Oct.
4. Van de Kerkhof PCM. Comparisons and combinations. In: van de Kerkhof PCM, editor. *Textbook of psoriasis*. Osney Mead (Oxford): Blackwell Science Ltd; 1999:275-283.
5. Krueger JG. The immunologic basis for the treatment of psoriasis with new biologic agents. *J Am Academy Dermatol* 2002;46:1-23.

9 Hospice Care

Subject: Hospice Care	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

This service requires a referral to the Community Health Plan's Case Management Division.

1. References:

CHP Case Management Hospice Care desk procedure.

10 Home Hospital Beds

Subject: Home Hospital Beds & Accessories	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

CHP utilizes Milliman Care guidelines regarding Home Health Care assessments for patient safety and Activities of Daily Living (ADLs). In addition, please refer to CHP's DME Formulary.

11 Hyperbaric Oxygen Therapy

Subject: Hyperbaric Oxygen Therapy	
<input type="checkbox"/> Original	Original Committee Approval: May 20, 2002
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

Clinical guidelines changed from CHP Criteria to Milliman CareGuidelines.

(**Note: CMS National/Local Coverage Determinations will apply for Medicare Advantage members as indicated.)

12 Medical Nutritional Therapy – Enteral Nutrition

Subject: Medical Nutritional Therapy – Enteral Nutrition	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

CHP utilizes DSHS Billing Guidelines for this service. In addition, for Medicare Advantage members, CMS Local and National Coverage Determinations also will be employed.

13 Occupational Therapy

Subject: Occupational Therapy	
<input type="checkbox"/> Original	Original Committee Approval: May 20, 2002
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

1. Definition:

Occupational therapy involves the use of purposeful activities to help people regain performance skills lost through injury or illness. The goal of such individualized programs is to improve a patient's quality of life by recovering competence, maximizing independence, and preventing injury or disability as much as possible.

2. Background:

Inpatient and/or outpatient rehabilitative therapies include occupational therapy and are sometimes required to restore, improve, or maintain a physical function affected by a covered illness or injury. Services must be provided by a licensed or registered occupational therapist.

3. Indications/Criteria:

Short-term occupational therapy is necessary in selected cases when a PCP or physician specialist prescribes this care and either of the following criteria applies:

- To provide task-oriented therapeutic activities designed to significantly improve, develop or restore physical functions lost or impaired as a result of a disease or injury,
- OR**
- To learn or relearn daily living skills (e.g., dressing, eating and bathing) or compensatory techniques to improve the level of independence in the activities of daily living.

In all cases, therapy must be designed to achieve a specific diagnosis-related goal for a patient who has a reasonable expectation of achieving measurable improvement in a reasonable and predictable period of time. The treatment provided must be specific, effective, and reasonable for the patient's diagnosis and physical condition.

4. Plan of Care:

Occupational therapy must be provided in accordance with an ongoing, written plan of care. The referring provider and the occupational therapist must sign the plan of care.

The plan of care must include:

- The date of onset or exacerbation of the disorder,
- Specifics regarding both long-term and short-term goals,
- Measurable objectives,
- A reasonable estimate of the timelines for the specific goals,
- Specifics regarding the treatment techniques and/or exercises to be employed, and
- The frequency and duration of treatment.

This Plan of Care must be updated as the patient’s condition changes and re-certified by the referring provider at 30-day intervals. This update must document the patient’s active participation/compliance in the prescribed program. Consistent progress towards achieving both the long-term and short-term goals must be documented along with an estimate of the total number of additional visits required to achieve the treatment plan.

5. Occupational Therapy Guidelines:

**See Milliman Care guidelines.

6. Limitations/Exclusions:

Healthy Options:	None; prior authorization required after 12 visits.
PEBB:	None; prior authorization required after 12 visits.
Basic Health Plan:	Covered in combination with Physical Therapy after joint reconstructive therapy; prior auth with first visit
GAU:	None; prior authorization required after 12 visits.
Medicare Advantage:	None; prior authorization with first visit

7. Required Approvals:

Prior authorization by CHP Medical Director or his/her designee.

8. References:

- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

14 Orenzia - Abatacept

Subject: Orenzia® - Abatacept	
<input type="checkbox"/> Original	Original Committee (P&T) Approval: March 10, 2006
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

1. Background:

Rheumatoid arthritis (RA) is a chronic, progressive, inflammatory, autoimmune disease affecting about 1% of the US adult population and occurs approximately 3 times more frequently in women than in men.ⁱ Almost 80% of RA cases occur in patients between 35 and 50 years of ageⁱⁱ (usually a time of peak social productivity). The disease is characterized by persistent inflammation of the synovium, cartilage loss, and bone erosion in peripheral joints, usually in a symmetric fashion. Research has shown that joint damage occurs within the first 2 years of symptoms and diagnosis and that it progresses rapidly if not treated.^{iii,iv,v} Although RA primarily affects the joints, it is a systemic disease and does cause systemic and extra-articular clinical features (e.g., fever, fatigue, anorexia, weight loss, and anemia). Patients with RA also have greater mortality than the general population.

RA immunopathology involves multiple cell types and signaling mechanisms (cytokines). Recent evidence suggests that T-cells substantially contribute to RA immunopathology, as evidenced by their presence in RA synovial specimens.^{vi} In order for T-cells to become fully activated and to contribute to the disease pathogenesis, they require two signals: one from antigen-specific T-cell receptors plus one via a non-antigen-specific costimulatory receptor, typically CD28. CD28 is expressed on T-cells and binds to both CD80 (B7-1) and CD86 (B7-2) on activated antigen-presenting cells.

Abatacept (CTLA-4Ig) is a first-in-class selective costimulation modulator. CTLA-4Ig is a soluble fusion protein comprised of the ligand-binding domain of CTLA-4 and the tail end of human immunoglobulin.^{vii} CTLA-4 is normally expressed on the cell surface of activated T-cells and on regulatory T-cells. It binds CD80 and CD86 with approximately 100-fold higher affinity than CD28.^{viii} This binding blocks full T-cell activation and proliferation and inhibits the production of various cytokines associated with inflammation including TNF-alpha, interferon gamma, and

interleukin-2. It is unknown if this cytokine modulation contributes to the drug's efficacy in RA.

Labeling for Orencia® indicates that clinical data from five pivotal, randomized, double-blind, placebo-controlled studies provided the evidence for its efficacy, safety, and approval for the treatment of adult patients with RA. Only one of these studies (Study 4) is currently fully published.^{viii} In Study 4, the efficacy and safety of abatacept was assessed in patients with an inadequate response to a TNFI; the TNFI was discontinued prior to randomization, but concurrent use of other disease-modifying antirheumatic drugs (DMARDs) was permitted. The proportion of patients achieving an ACR 20, 50, or 70 response at 6-months was significantly greater in the group receiving abatacept + DMARDs compared with the group receiving placebo + DMARDs (all $P < .01$). In addition, a greater proportion of patients receiving abatacept + DMARDs achieved a clinically and statistically significant improvement in Health Assessment Questionnaire (HAQ) disability index scoring compared with the group receiving placebo + DMARDs ($P < .001$). Abatacept was also well tolerated; headache was the only adverse event that occurred more frequently in the group receiving abatacept compared with control. Other fully published clinical trials for abatacept include one 6-month phase 2 study^x, its 6-month extension^x, and a pilot study^{xi}.

In total (published and unpublished), clinical trial evidence consistently indicates the agent has clinical benefit for treatment-refractory RA patients (in terms of ACR response, improvement in HAQ disability index, and radiographic response), at least in combination with stable doses of concurrent DMARDs. There are no head-to-head comparative clinical studies with biologic DMARDs, and because many of the phase 3 clinical trials are not fully published, relative efficacy and safety compared to biologic DMARDs cannot be established at this time. Current safety data indicates some issues: a higher incidence of serious infections when used in combination with TNFIs and a greater incidence of adverse effects, including worsening of respiratory status in patients with concurrent COPD. Availability of longer-term (>1 year) safety data is limited; while such evidence for the newer biologic DMARDs consists of substantial patient-years.

2. Indications/Criteria:

The use of abatacept may be considered medically necessary in patients (age ≥ 18 years) meeting all of the following criteria:

- Moderate to severe RA (Stage II-III) as defined by American College of Rheumatology has been diagnosed,
- Patient is on stable doses of DMARDs,

- There has been a previous trial and failure with one formulary TNF-alpha inhibitor (TNFI) (Enbrel[®] or Humira[™]), or contraindications to use of a TNFI are present,
- Patient's therapeutic plan does not include concurrent therapy with a TNFI (e.g., adalimumab, Humira[™]; etanercept, Enbrel[®]; or infliximab, Remicade[®]) or anakinra, Kineret[™], and
- Dosing does not exceed 1000 mg every 2 weeks x 3 doses (initial load), then 1000 mg every 4 weeks.

The use of abatacept will be considered investigational for the treatment of patients with other types of arthropathies and/or other pathological indications.

3. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

4. Required Review and Approvals:

Orencia[®] (abatacept) requires prior authorization by the CHP Medical Director or his/her designee. Each authorization period will be for six months.

5. References:

ⁱ American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines. Guidelines for the management of rheumatoid arthritis: 2002 update. *Arthritis Rheum* 2002;46:328-46.

ⁱⁱ Kavanaugh AF, Lipsky PE. Rheumatoid arthritis. In: Rich RR, Fleisher TA, Schwartz B et al, editors. *Clinical Immunology: Principles and Practice*. St. Louis (MO): Mosby-Year Book; 1996. p. 1093-116.

ⁱⁱⁱ van der Heijde DMFM, van Leeuwen MA, van Riel PLCM, et al. Biannual radiographic assessments of hands and feet in a three-year prospective followup of patients with early rheumatoid arthritis. *Arthritis Rheum* 1992;35:26-34.

^{iv} Plant MJ, Saklatvala J, Borg AA, Jones PW, Dawes PT. Measurement and prediction of radiological progression in early rheumatoid arthritis. *J Rheumatol* 1994;21:1808-13.

^v van der Heijde DM. Joint erosions and the patient with early rheumatoid arthritis. *Br J Rheumatol* 1995;34 Suppl 2:74-8.

^{vi} Cron RQ. A signal achievement in the treatment of arthritis. *Arthritis Rheum* 2005;52(8):2229-32.

^{vii} Orencia[®] (abatacept) prescribing information. Princeton (NJ): Bristol-Myers Squibb Company; 2005.

^{viii} Genovese MC, Becker J-C, Schiff M, et al. Abatacept for rheumatoid arthritis refractory to tumor necrosis factor- α inhibition. *N Engl J Med* 2005;353:1114-23.

^{ix} Kremer JM, Westhovens R, Leon M, et al. Treatment of rheumatoid arthritis by selective inhibition of T-cell activation with fusion protein CTLA-4Ig. *N Engl J Med* 2003;349:1907-15.

^x Kremer JM, Dougados M, Emery P, et al. Treatment of rheumatoid arthritis with the selective costimulation modulator abatacept. Twelve-month results of a phase IIb, double-blind, randomized, placebo-controlled trial. *Arthritis Rheum* 2005;52(8):2263-71.

^{xi} Moreland LW, Alten R, Van den Bosch F, et al. Costimulatory blockade in patients with rheumatoid arthritis. A pilot, dose-finding, double-blind, placebo-controlled clinical trial evaluating CTLA-4Ig and LEA29Y eighty-five days after the first infusion. *Arthritis Rheum* 2002;46(6):1470-9.

15 Orthotics

Subject: Orthotics	
<input type="checkbox"/> Original	Original Committee Approval: August 27, 2003
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

Please refer to CHP's DME Formulary.

16 Oxygen, Supplemental

Subject: Oxygen, Supplemental	
<input type="checkbox"/> Original	Original Committee Approval: December 15, 2004
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

Clinical guidelines changed from CHP Criteria to Milliman CareGuidelines.

17 Patient Lifts

Subject: Patient Lifts	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

Please refer to CHP's DME Formulary.

18 Reconstructive Plastic Surgery

Subject: Reconstructive Plastic Surgery	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

Please refer to Benefit Grids for all CHP lines of business. **Note Cosmetic Surgery is a benefit exclusion for all CHP lines of business.

19 Rehabilitation (Inpatient)/Skilled Nursing Facility

Subject: Rehabilitation (Inpatient)/Skilled Nursing Facility	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1998
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

1. Background:

Patients appropriate for Skilled Nursing Facility (SNF) admission are those who meet Medicare Criteria, who are in the sub-acute phase of illness and who need medical and continuous nursing services. These services require Case Management referral.

2. Indications/Criteria:

Level 1 (Routine Care):	Patient is medically stable but requires 24-hour skilled nursing observation, assessment, monitoring and intervention, under physician supervision. Treatment goals are to restore function and to train the individual to independently meet his/her activities of daily living. Examples of Level I care include routine respiratory treatments, simple tracheostomy care, tube feedings, catheterizations, IV therapy, simple wound care, ostomy care, traction and positioning, etc.
Level II (Rehabilitative Care):	Patient is medically stable but requires 24-hour skilled nursing observation, assessment, monitoring and intervention, under physician supervision. Treatment goals are to restore function, increase strength and endurance and to train the individual to independently do his/her activities of daily living. Examples of Level II care include all of the above PLUS whirlpool treatments, 1 hour/day of PT, OT, or ST, etc.
Level III (Rehabilitative Subacute Care):	Patient requires more complex medical care with more intensive therapy interventions to improve functional outcomes. The services are directly and specifically related to an active treatment plan designed by the physician and at a level of complexity that requires the judgment, knowledge and skills of a qualified physical therapist (if rehabilitation is required). Examples of Level III care include all of the above PLUS higher level respiratory therapy monitoring, stage III decubitus ulcers, complex wound care, > 2 hours/day of PT/OT/ST, etc.
Level IV (Rehabilitative Subacute Care):	Patient requires multiple treatments for multiple comorbidities. Examples of Level IV care include all of the above PLUS ventilator weaning, stage IV decubitus ulcers, BID labs, > 3 hours/day of PT/OT/ST, etc.

3. Limitations/Exclusions:

Custodial Care is not a covered benefit. Custodial care may include:

- Administration of routine oral medications, eye drops and ointments,
- General maintenance of a colostomy or ileostomy,
- Routine indwelling bladder catheter care,
- Dressing changes for chronic conditions,
- Routine care of the incontinent patient,
- Assistance with ADL's, or
- Periodic turning and positioning in bed.

Each of these supportive services is not normally skilled, but can still be a part of SNF care; however, they do not qualify a patient for a SNF level of care.

4. Guidelines:

Please see Milliman Care guidelines.

Healthy Options:	Rehab is covered; SNF is not covered by CHP unless Aging and Adult Services Division of DSHS denies coverage. Prior authorization required
PEBB:	Covers in-patient rehabilitation to a maximum of 60 days per calendar year; SNF is covered. Prior authorization required
Basic Health Plan:	Rehab is not covere; SNF is covered if it is an alternative to hospitalization in an acute setting. Prior authorization required
GAU:	Acute Rehab is covered by DSHS; SNF is covered if it is an alternative to hospitalization in an acute setting. Prior authorization required
Medicare Advantage:	Covered. Use CMS NCDs

5. Required Approvals:

Prior authorization by the CHP Medical Director or his/her designee.

6. References:

- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate for Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

20 Remicade™ (Infliximab)

Subject: Remicade™ (Infliximab)	
<input type="checkbox"/> Original	P&T Committee Approval: October 13, 2006
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 13, 2006

Changed from Milliman Care guidelines to CHP in-house guidelines.

1. Background:

Infliximab is a genetically engineered chimeric murine/human monoclonal antibody specifically directed against tumor necrosis factor-alpha (TNF-alpha). Its binding of both soluble and transmembrane TNF-alpha inhibits TNF-alpha's interaction with its receptors, reducing its biologic activity.^{xii} Tumor necrosis factor (TNF) is a cytokine produced by macrophages and T-cells. Research has revealed that TNF has a broad spectrum of biologic functionality. In particular, it is a key mediator of inflammation and is produced in response to infection and immunologic injury. Elevated concentrations of TNF-alpha have been found in the joints of rheumatoid arthritis patients and in the stools of Crohn's disease patients and have been correlated with increased disease activity.

Infliximab received FDA approval in August 1998 for the treatment of moderately to severely active Crohn's disease in patients with an inadequate response to conventional therapies, and treatment of patients with fistulizing Crohn's disease for the reduction in the number of draining enterocutaneous fistula(s). Since that time, supplemental Biologics License Applications have been approved for infliximab for the following additional uses:^{xiii}

- Moderately to severely active rheumatoid arthritis in combination with methotrexate,
- Reducing the signs and symptoms of active arthritis in patients with psoriatic arthritis,
- Moderate to severe ulcerative colitis in patients who have not responded well to other therapy,
- Moderate to severe plaque psoriasis in patients who have not responded well to other therapy, and
- Reducing the signs and symptoms of active ankylosing spondylitis.

Infliximab is administered parenterally; therefore, it is not covered under retail pharmacy benefits.

2. Indications/Criteria:

The use of infliximab may be considered medically necessary for its labeled indications of:

Crohn's

Fistulizing Crohn's disease or inducing and maintaining clinical remission in patients with moderately to severely active Crohn's disease in patients with an inadequate response or intolerance to conventional therapy: Conventional therapy, for the purpose of this policy, includes the use of 3 or more of the following:

- corticosteroids (e.g., prednisone, prednisolone, dexamethasone, budesonide),
- sulfasalazine,
- immunomodulatory drugs (e.g., azathioprine, mercaptopurine, cyclosporine, methotrexate),
- 5-aminosalicylic acid (brand names include Rowasa[®], Pentasa[®] and Asacol[®]) and
- antibiotics (e.g., metronidazole, quinolones).

Colitis

Moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy: Conventional therapy, for the purpose of this policy, includes the use of the following:

- topical and oral aminosalicylates,
- topical, oral or IV corticosteroids,
- oral or IV immunotherapy (e.g., azathioprine, 6-mercaptopurine, cyclosporine) and
- surgery for refractory disease.

Rheumatoid Arthritis

Moderately- to severely-active rheumatoid arthritis when used in combination with methotrexate AND history of an adequate (≥ 12 week) trial and therapeutic failure or intolerance with at least one formulary (preferred) TNF-alpha inhibitor (etanercept).

Psoriatic Arthritis

Active psoriatic arthritis AND history of an adequate (≥ 12 week) trial and therapeutic failure or intolerance with at least one formulary (preferred) TNF-alpha inhibitor (etanercept).

Ankylosing Spondylitis

Active ankylosing spondylitis refractory to conventional therapy AND history of an adequate (≥ 12 week) trial and therapeutic failure or intolerance with at least one formulary (preferred) TNF-alpha inhibitor (etanercept). Conventional therapy, for the purpose of this policy, includes the use of at least 3 of the following:

- nonsteroidal anti-inflammatory drugs (NSAIDs),

- immunomodulatory agents (e.g., methotrexate, azathioprine, mercaptopurine, cyclosporine),
- local steroid injections or
- sulfasalazine.

Plaque psoriasis

Chronic moderate to severe plaque psoriasis (psoriasis vulgaris) AND meeting all the following additional criteria:

- Involvement of $\geq 10\%$ of the patient's body surface area (BSA). Exceptions may be considered for extensive recalcitrant facial involvement, pustular involvement of the hands or feet, and/or genital involvement interfering with normal sexual function,
- History of an adequate trial and treatment failure with phototherapy or photochemotherapy or such treatment is contraindicated, not tolerated, or unavailable,
- History of an adequate trial and treatment failure with ≥ 1 approved systemic therapy (e.g., methotrexate) or such treatment is contraindicated or not tolerated, and
- History of an adequate (≥ 12 week) trial and therapeutic failure or intolerance with at least one formulary (preferred) TNF-alpha inhibitor (etanercept).

3. Authorization guidelines:

1. Crohn's disease:

- Initial therapy with up to 5 infusions in a 6-month period when the criteria listed above are met. The 5 infusions include the recommended loading dose of 5 mg/kg at weeks 0, 2, and 6, plus a maintenance infusion every 8 weeks.
- Retreatment may be approved at a maximum of 6 infusions in a 12-month time period based on the following criteria:
 - Patient met initial coverage criteria listed above,
 - A significant/sustained response to the last infliximab course is documented in the patient's progress notes, and
 - History that either azathioprine or mercaptopurine was not effective at maintaining remission, use of these agents was contraindicated, or they were not tolerated.
- For patients who respond and then lose their response, adjusting the dosing frequency to as often as every 4 weeks or increasing the dose to 10 mg/kg, but not both concurrently, may be approved.

2. Ulcerative colitis:

- Initial therapy with up to 5 infusions in a 6-month period may be approved when the criteria listed above are met. The 5 infusions include the recommended loading dose of 5 mg/kg at weeks 0, 2, and 6, plus a maintenance infusion every 8 weeks.
- Retreatment may be approved at a maximum of 6 infusions in a 12-month time period based on the following criteria:

- a) Patient met initial coverage criteria listed above, and
 - b) A significant/sustained response to the last infliximab course is documented in the patient progress notes.
3. Rheumatoid Arthritis:
- Initial therapy with up to 5 infusions of 3 mg/kg infliximab in a 6-month period, in combination with methotrexate, may be approved. The 5 infusions include the recommended loading doses at weeks 0, 2, and 6, plus an infusion every 8 weeks for maintenance.
 - Retreatment with infliximab may be approved at a maximum of 6 infusions in a 12-month time period based on the following criteria:
 - a) * An improvement in any 1 of the following American College of Rheumatology assessment components for improvement:
 - painful joint count,
 - swollen joint count,
 - patient pain assessment,
 - patient global assessment,
 - physician global assessment,
 - patient self-assessed disability, or
 - acute phase reactants (ESR or CRP).
 - b) For patients with an incomplete response, adjusting the dosing frequency to as often as every 4 weeks or increasing the dose to a maximum of 10 mg/kg, but not both concurrently, may be approved.
4. Psoriatic Arthritis:
- Initial therapy with up to 5 infusions in a 6-month period may be approved when the criteria listed above are met. The 5 infusions include the recommended loading dose of 5 mg/kg at weeks 0, 2, and 6, plus a maintenance infusion every 8 weeks.
 - Retreatment may be approved at a maximum of 6 infusions in a 12-month time period based on the following criteria:
 - a) Patient met initial coverage criteria listed above, and
 - b) A significant/sustained response to the last infliximab course is documented in the patient progress notes.
5. Ankylosing Spondylitis:
- Recommended dosing of infliximab for this indication includes an initial load of three IV infusions at 5 mg/kg over a 6-week timeframe (weeks 0, 2 and 6). Coverage of retreatment (single 5 mg/kg doses every 6 weeks or more as needed) will require documentation of maintenance or improvement in disease severity before the first retreatment, and every six months thereafter.
 - Baseline disease severity indices should be submitted so that treatment efficacy can be evaluated after the initial course. Such indices may include tender and swollen joint counts, patient global assessment, physician global assessment,

patient pain assessment, levels of acute phase reactants (e.g., ESR, CRP), BASDAI score or ASAS response.

6. Plaque Psoriasis:

- Initial therapy with up to 5 infusions of 5 mg/kg of infliximab in a 6-month period may be approved. The 5 infusions include the recommended loading doses at weeks 0, 2, and 6, plus a maintenance infusion every 8 weeks. No additional benefit was observed for a dose of 10 mg/kg.
- Retreatment with infliximab may be approved at a maximum of 6 infusions in a 12-month time period based on objective documentation of effectiveness.

7. General:

- Retreatment should be terminated if the patient develops symptoms of antibody reaction, such as myalgias, rash, fever and polyarthralgia, which have been reported to occur 2 or more years after the initial infusion in patients who continue to receive retreatment.
- Patients not responding to therapy after 14 weeks are unlikely to respond, and consideration should be given to discontinuing infliximab therapy.
- The use of infliximab may be considered investigational for the treatment of patients with:
 - a) Sarcoidosis,
 - b) Graft vs Host Disease,
 - c) Sjögren’s Syndrome,
 - d) Uveitis, or
 - e) Other pathological indications and/or arthropathies.

4. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

5. Required Review and Approvals:

Infliximab (Remicade®) infusions require prior authorization by the CHP Medical Director or his/her designee. Initial authorization period will be for six months. Subsequent re-authorization periods will be as specified above.

6. References:

^{xii} Centocor, Inc. Remicade® (infliximab recombinant) prescribing information. Centocor, Inc; 2005 Sep.

^{xiii} US Food and Drug Administration Center for Drug Evaluation and Research. Infliximab Approval History. [Online]. [cited 2006 May 18]. Available from:
URL:<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.LabelApprovalHistory#apphist>.

21 Rituxan™ (Rituximab)

Subject: Rituxan™ (Rituximab)	
<input checked="" type="checkbox"/> Original	Original P&T Committee Approval: October 13, 2006
<input type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 13, 2006

**Note: Prior authorization for this IV medication is only required for Rheumatoid Arthritis. Please refer to the specific RA criteria (highlighted) below.

1. Background:

Rituximab is a genetically engineered chimeric murine/human monoclonal antibody specifically directed against CD20, a transmembrane protein found on the surface of B-cells.^{xiv} CD20 is expressed on >90% of B-cell non-Hodgkin's lymphomas (NHL),^{xv} but is not found on hematopoietic stem cells, pro-B cells, normal plasma cells or other normal tissues.^{xvi} CD20 regulates early steps in the activation process for cell cycle initiation and differentiation,^{xvi} and possibly functions as a calcium ion channel.^{xvii} B-cells are also now believed to play a role in the pathogenesis of rheumatoid arthritis at multiple sites in the autoinflammatory process including production of rheumatoid factor and other autoantibodies, antigen presentation, T-cell activation, and proinflammatory cytokine production.^{xiv}

Rituximab received FDA approval in November 1997 for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma (NHL). In April 2001, a supplemental Biologics License Application was approved for Rituxan for these additional uses: retreatment of patients with rituximab who have relapsed following initial rituximab therapy, use of eight weekly doses (compared to original four) per course of treatment, and treatment of patients with bulky disease (lesions > 10 cm). In February 2006, the FDA approved rituximab for the first-line treatment of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma (DLBCL- a type of NHL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens. Also in February 2006, the FDA approved rituximab in combination with methotrexate for the treatment of moderately- to severely-active rheumatoid arthritis in patients who have had an inadequate response to one or more TNF antagonist therapies.^{xviii}

Rituximab is administered parenterally. Therefore, it is not generally covered under retail pharmacy benefits. Availability of published evidence for its use in

patients with RA is currently limited,^{xiv}, ^{xix}, ^{xx}, ^{xxi} and long-term efficacy and safety remains a concern.

In a randomized, controlled, phase 3 trial, rituximab was also demonstrated effective and relatively safe for the treatment of patients with mantle cell lymphoma.^{xxii} One hundred twenty two patients with untreated advanced-stage mantle cell lymphoma were treated with 6 cycles of CHOP plus rituximab (n=62) or CHOP alone (n=60). Chemotherapy plus rituximab was significantly superior to chemotherapy alone in terms of overall response rate (94% vs. 75%; P = .0054), complete remission rate (34% vs. 7%; P = .00024), and time to treatment failure (TTF; median, 21 vs. 14 months; P = .0131). No differences were observed for progression-free survival. Toxicity was acceptable, with no major differences between the two therapeutic groups.

****FDA Warning (Posted 12/18/2006):**

FDA and Genentech informed healthcare professionals of important emerging safety information about Rituxan. Two patients died after being treated with Rituxan for systemic lupus erythematosus (SLE). Rituxan is approved for the above indication and is prescribed off-label for other serious diseases and conditions such as SLE. The cause of death was a viral infection of the brain called progressive multifocal leukoencephalopathy (PML) that is caused by reactivated JC virus which is present in about 80 percent of adults. Physicians should maintain a high index of suspicion for the development of PML in patients under treatment with Rituxan.

2. Indications/Criteria:

The use of rituximab may be considered medically necessary for its labeled indications of:

- Low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma (NHL), including patients who have relapsed following initial rituximab therapy,
- Diffuse large B-cell, CD20-positive NHL (DLBCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens, and
- Moderately- to severely-active rheumatoid arthritis in patients with a history of an adequate (≥12 week) trial and failure with at least one formulary TNF-alpha inhibitor (TNFI), or with the presence of contraindications to the use of a TNFI.

The use of rituximab may also be considered medically necessary for treatment of patients with the following off-label indications:

- Mantle cell lymphoma, or
- Eradication of inhibitors in patients with hemophilia who had an inadequate response or developed intolerance to other conventional immune modulatory therapies (e.g., corticosteroids, cyclophosphamide), or when use of these agents is relatively or absolutely contraindicated.

Authorization should be limited to:

- An eight infusion course in CD20-positive, relapsed or refractory, low-grade or follicular B-cell NHL, DLBCL, or mantle cell lymphoma,
- Four infusions (2 courses) per year at a dose not to exceed 1000 mg in patients with RA, or
- Four weekly infusions at a dose of 375 mg/m² for eradication of inhibitors in patients with hemophilia.
- The use of rituximab may be considered investigational for the treatment of patients with other pathological indications and/or arthropathies.

3. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

4. Required Review and Approvals:

Rituximab (Rituxan®) infusions require prior authorization by the CHP Medical Director or his/her designee.

5. References:

- xiv Genentech, Inc. Rituxan® (rituximab) prescribing information. South San Francisco (CA): Genentech, Inc; 2006 Feb.
- xv Anderson KC, Bates MP, Slaughenhaupt BL, et al. Expression of human B cell-associated antigens on leukemias and lymphomas: A model of human B cell differentiation. *Blood* 1984;63(6):1424-1433.
- xvi Tedder TF, Boyd AW, Freedman AS, et al. The B cell surface molecule B1 is functionally linked with B-cell activation and differentiation. *J Immunol* 1985;135(2):973-9.
- xvii Tedder TF, Zhou LJ, Bell PD, et al. The CD20 surface molecule of B lymphocytes functions as a calcium channel. *J Cell Biochem* 1990;14D:195.
- xviii US Food and Drug Administration Center for Drug Evaluation and Research. Rituximab Approval History. [Online]. [cited 2006 May 17]. Available from URL: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist.
- xix Cohen SB, Greenwald M, Dougados MR, et al. Efficacy and safety of rituximab in active RA patients who experienced an inadequate response to one or more anti-TNF a therapies (REFLEX study). Presented at: The Annual Scientific Meeting of the American College of Rheumatology: Abstract #1830; 2005 Nov 12-17. San Diego (CA).
- ^{xx} Emery P, Filipowicz-Sosnowska A, Szczepanski L, et al. Primary analysis of a double-blind, placebo-controlled, dose-ranging trial of rituximab, an anti-CD20 monoclonal antibody, in patients with rheumatoid arthritis receiving methotrexate (DANCER trial). Presented at: The European League Against Rheumatism Meeting: Abstract #OP0008; 2005. Vienna (Austria).
- ^{xxi} Emery P, Fleischmann RM, Filipowicz-Sosnowska A, et al. Rituximab in rheumatoid arthritis: a double-blind, placebo-controlled, dose-ranging trial. Presented at: The 2005 ACR/ARHP Annual Scientific Meeting: Abstract #1917; 2005 Nov 12-17. San Diego (CA).
- ^{xxii} Lenz G, Dreyling M, Hoster E, et al. Immunochemotherapy with rituximab and cyclophosphamide, doxorubicin, vincristine and prednisone significantly improves response time to treatment failure, but not long-term outcome in patients with previously untreated mantle cell lymphoma: results of a prospective randomized trial of the German Low Grade Lymphoma Study Group (GLSG). *J Clin Oncol* 2005;23(9):1984-1992.

22 Speech Therapy

Subject: Speech Therapy	
<input type="checkbox"/> Original	Original Committee Approval: May 20, 2002
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

NOTE: CHP Guidelines are used for pediatric requests; Milliman CareGuidelines (with annotations below) are used for adult requests

1. Background:

Speech therapy involves rehabilitation of communication impairment and swallowing disorders.

Inpatient and/or outpatient rehabilitative therapies (including speech therapy) are sometimes required to restore, improve, or maintain a physical function affected by a covered illness or injury. Services must be provided by a licensed or registered certified speech therapist.

2. Indications/Criteria:

- To restore or improve speech or swallowing in members who have speech-language disorders that are the result of a non-chronic disease or acute injury,
- Speech delay that is associated with a specifically diagnosable disease, injury, or congenital defect (e.g., cleft palate, cleft lip, etc.), and
- Developmental delay in those children with expressive language impairments.

The plan will not cover speech therapy for children with the following conditions:

- Dysfunctions that are self-correcting, such as in young children with natural dysfluency or articulation errors that resolve over time, and
- Conditions that are frequently encountered in school settings and in developmental learning centers:
 1. Behavioral problems,
 2. Attention disorders,
 3. Psychosocial speech delay,
 4. Mental retardation, or
 5. Conceptual handicap.

Note: For school-age children, the PCP should first investigate the local school district's speech therapy program prior to referral to contracted specialists.

3. Plan of Care:

In all cases, therapy must be designed to achieve a specific diagnosis-related goal for a patient who has a reasonable expectation of achieving measurable improvement in a reasonable and predictable period of time. The treatment provided must be specific, effective, and reasonable for the patient’s diagnosis and physical condition.

Speech therapy must be provided in accordance with an ongoing, written plan of care. The referring provider and the occupational therapist must sign the plan of care. The Plan of Care must include:

- The date of onset or exacerbation of the disorder,
- Specifics regarding both long-term and short-term goals,
- Measurable objectives,
- A reasonable estimate of the timelines for the specific goals,
- Specifics regarding the treatment techniques and/or exercises to be employed, and
- The frequency and duration of treatment.

This Plan of Care must be updated as the patient’s condition changes, and must be re-certified by the referring provider after an initial 30 days. Subsequent re-certification may be authorized at 90-day intervals if the condition is chronic. These updates must document the patient’s active participation/compliance in the prescribed program. Consistent progress towards achieving both the long-term and short-term goals must be documented along with an estimate of the total of additional visits required to achieve the treatment goal.

4. Speech Therapy Guidelines:

Please refer to Adult and Pediatric criteria above.

5. Limitations/Exclusions:

Healthy Options:	None. Pre-authorization required after initial 12 visits
PEBB:	None.
Basic Health Plan:	Speech therapy is not a covered benefit.
GAU:	None. Pre-authorization required after initial 12 visits
Medicare Advantage:	None. Pre-authorization required for first visit

6. Required Approvals:

Speech Therapy requires prior authorization by CHP Medical Director or his/her designee.

7. References:

- Milliman Care guidelines 2006.
- Aetna. Speech Therapy. Aetna Clinical Policies 2006 Aug 19;(Bulletin # 0243).
- Premera. Speech Therapy. Premera Corporate Medical Policy 2005 May 11;(#8.03.04).
- Speech and language therapy for aphasia following stroke. Cochrane Library Review 1999 Jul 13;(Abstract #AB00245).
- Speech and language therapy for children with Cerebral Palsy. Cochrane Library Review 2003 Mar 27;(Abstract #AB003466).
- Speech and language interventions for children with primary language delay or disorder. Cochrane Library Review 2003 May 9;(Abstract #AB004110).
- MAA Speech Audiology Billing Instructions 1996 Jul;(WAC #388-545-0700).
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

23 Suction Pumps

Subject: Suction Pumps	
<input type="checkbox"/> Original	Original Committee Approval: December 15, 2004
<input checked="" type="checkbox"/> Revised	Last Committee Review: December 20, 2006
	Last Review: November 2006

1. Background:

A portable home model suction pump is a lightweight, compact, electric aspirator designed for upper respiratory oral pharyngeal and tracheal suction for use in the home. Use of the device does not require technical or professional supervision.

Home model suction machines are medically necessary durable medical equipment for patients who have difficulty raising and clearing secretions secondary to any of the following conditions:

- Cancer or surgery of the throat or mouth,
- Dysfunction of the swallowing muscles,
- Unconsciousness or obtunded state,
- Tracheostomy, or
- Insufficient development or coordination of the swallowing muscles in infants.

2. Supplies:

Tracheal suction catheters are considered medically necessary supplies for suction pumps. In most cases, in the home setting, sterile catheters are considered medically necessary only for tracheostomy suctioning. Three suction catheters per day are considered medically necessary for tracheostomy suctioning, unless additional documentation is provided. When a tracheal suction catheter is used in the oropharynx, which is not sterile, the catheter can be reused if properly cleansed and/or disinfected. In this situation the medical necessity for more than three catheters per week would require additional documentation.

Sterile saline solution is considered medically necessary when used to clear a suction catheter after tracheostomy suctioning. It is not usually considered medically necessary for oropharyngeal suctioning. Note: saline used for tracheal lavage is a non-covered supply.

The following supplies are considered medically necessary for use with a suction pump:

- Oropharyngeal suction catheters,
- Disposable or non-disposable canister used with suction pump, and

- Tubing used with suction pump.
- When a suction pump is used for tracheal suctioning, other supplies (e.g., cups, basins, gloves, solutions, etc.) included with the tracheal care kit are considered medically necessary. When a suction pump is used for oropharyngeal suctioning, these other supplies are not considered medically necessary.

3. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	DME benefit limit of \$500 / calendar year
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

4. Required Review and Approvals:

Suction pump rental requires prior authorization by CHP Medical Director or his/her designee.

5. References:

- Aetna. Suction Pumps. Aetna Clinical Policies Manual 2006 Aug 29;(#0503).
- CMS Coverage Manual. [Online]. Available from URL:<http://www.cms.hhs.gov/mcd/>
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

 24 Temporomandibular Joint Dysfunction (TMJ)

Subject: Temporomandibular Joint Dysfunction (TMJ)	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

1. Background:

Temporomandibular Joint Dysfunction (TMJ) is a condition in which there is an anatomical abnormality of the temporomandibular (jaw) joint. This is most commonly the result of malocclusion of the teeth, muscle spasm (bruxism or jaw clenching), or trauma. Patients with TMJ typically complain of orofacial pain, restricted jaw opening, and noise in the joint (clicking or popping). Treatment may include oral appliances ("bite splints"), physical therapy, medications (NSAIDs and other analgesics), behavioral therapy, psychotherapy, and surgery. To date, there is a lack of compelling evidence supporting any particular intervention over another. Expert consensus remains that conservative, reversible therapy is the best and safest approach in managing this complex and poorly understood disorder.

2. Indications/Criteria:

The diagnosis of TMJ is largely based upon the symptoms of pain and biological variables (e.g., joint sounds, variations of disc position within the joint, clicking, limited range of motion, etc.). Imaging studies can be used to confirm diagnosis, particularly in severe cases and in those that are pre-surgical. CT and MRI are currently indicated only for surgical candidates. Conservative therapy is effective in over 80% of cases, and surgery is indicated in fewer than 5% of patients.

3. Covered Services: (See also Limitations/ Exclusions.)

- Conservative management by PCP to include pharmacologic therapy, self-applied heat/other modalities and self-guided home physical therapy exercises (minimum of three months),
- Referral to either a cognitive behavioral therapist or biofeedback practitioner or acupuncturist for a maximum of 6 visits to promote relaxation techniques, or
- Bite plate or splint (excluded for BHP and PEBB).

4. Limitations/Exclusions:

Basic Health Plan:	No medical coverage except for initial evaluation and diagnosis. Dental services are not covered.
PEBB:	Only medical treatment is covered. Orthognathic surgery, dental implants, upper and/or lower jaw augmentation or reduction are specific exclusions and not covered.
Healthy Options:	Medical treatment for TMJ is covered. Dental services are not covered.
GAU:	Not covered
Medicare Advantage:	None. Pre-authorization is required

5. Required Approvals:

Treatment for TMJ/MPD requires prior authorization by the CHP Medical Director or his/her designee.

6. References:

- Aetna. Temporomandibular Joint Syndrome and Temporomandibular Disorder. Aetna Clinical Policies 2006 Feb 21 ;(Bulletin #0028). [Online]. Available at: URL:<http://www.aetna.com>.
- Hayes Inc. Online.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

25 Transmyocardial Laser Revascularization (TMLR)

Subject: Transmyocardial Laser Revascularization (TMLR) & Percutaneous TMLR (PTMR)

<input type="checkbox"/> Original	Original Committee Approval: February 8, 2002
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

Clinical guidelines changed from CHP Criteria to Milliman CareGuidelines.

26 Transplant: Bone Marrow

Subject: Transplant: Bone Marrow	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

1. Background:

This service requires a referral to Community Health Plan’s Case Management Department.

2. Coverage and Limitations:

Healthy Options:	Covered benefit.
PEBB:	Covered benefit.
Basic Health Plan:	Transplant services may be covered after a 12-month waiting period. (This may be waived for newborns and sudden onset of disease.)
GAU:	Covered by DSHS
Medicare Advantage:	Covered benefit. Use CMS NCDs & must be performed in a Medicare-approved facility

3. Required Approvals:

Pre-authorization by CHP Medical Director or h/her designee.

4. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- 2006 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

27 Transplant Work-ups/Donor Search/Donation

Subject: Transplant Work-ups/Donor Search/Donation	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

NOTE: Interlink criteria are used to review transplant-related requests.

These services require a referral to Community Health Plan’s Case Management Department. General information pertaining to specific solid organ transplants is listed in accompanying criteria sets.

1. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental Criteria: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- Benefit Grids.
- CHP Case Management Transplant Desk Procedure.

28 Transplant – Heart

Subject: Transplant – Heart	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

NOTE: Interlink criteria are used to review transplant-related requests.

1. Background:

This service requires a referral to Community Health Plan’s Case Management Department.

2. Coverage and Limitations:

Healthy Options:	Covered benefit.
PEBB:	Covered benefit.
Basic Health Plan:	Transplant services may be covered after a 12-month waiting period. (This may be waived for newborns and sudden onset of disease.)
GAU:	Covered by DSHS
Medicare Advantage:	Covered benefit. Use CMS NCDs & must be performed in a Medicare-approved facility

3. Required Approvals:

Transplant services require prior authorization by the Plan Medical Director Director or his/her designee.

4. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- 2006 – 2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

29 Transplant – Heart/Lung

Subject: Transplant – Heart/Lung	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

NOTE: Interlink criteria are used to review transplant-related requests.

1. Background:

This service requires a referral to Community Health Plan’s Case Management Department.

2. Coverage and Limitations:

Healthy Options:	Covered benefit.
PEBB:	Covered benefit.
Basic Health Plan:	Transplant services may be covered after a 12-month waiting period. (This may be waived for newborns and sudden onset of disease.)
GAU:	Covered by DSHS
Medicare Advantage:	Covered benefit. Use CMS NCDs & must be performed in a Medicare-approved facility

3. Required Approvals:

Transplant services require prior authorized by the Plan Medical Director or her/his designee.

4. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- 2006-2007 Healthy Options Contract.
- 2006BHP Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

30 Transplant – Kidney

Subject: Transplant – Kidney	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

NOTE: Interlink criteria are used to review transplant-related requests.

1. Background:

This service requires a referral to Community Health Plan’s Case Management Department.

2. Coverage and Limitations:

Healthy Options:	Covered benefit.
PEBB:	Covered benefit.
Basic Health Plan:	Transplant services may be covered after a 12-month waiting period. (This may be waived for newborns and sudden onset of disease.)
GAU:	Covered by DSHS
Medicare Advantage:	Covered benefit. Use CMS NCDs & must be performed in a Medicare-approved facility

3. Required Approvals:

Transplant services require prior authorization by the Plan Medical Director or her/his designee.

4. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

31 Transplant – Kidney/Pancreas (NOT Islet Cell)

Subject: Transplant – Kidney/Pancreas (NOT Islet Cell)	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

NOTE: Interlink criteria are used to review transplant-related requests.

1. Background:

This service requires a referral to Community Health Plan’s Case Management Department.

2. Coverage and Limitations:

Healthy Options:	Covered benefit.
PEBB:	Covered benefit.
Basic Health Plan:	Transplant services may be covered after a 12-month waiting period. (This may be waived for newborns and sudden onset of disease.)
GAU:	Covered by DSHS
Medicare Advantage:	Covered benefit. Use CMS NCDs & must be performed in a Medicare-approved facility

3. Required Approvals:

Transplant services require prior authorized by Plan Medical Director or her/his designee.

4. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

32 Transplant – Liver

Subject: Transplant – Liver	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: November 2006

NOTE: Interlink criteria are used to review transplant-related requests.

1. Background:

This service requires a referral to Community Health Plan’s Case Management Department.

2. Limitations/Exclusions:

Healthy Options:	Covered benefit.
PEBB:	Covered benefit.
Basic Health Plan:	Transplant services may be covered after 12-month waiting period. (This may be waived for newborns or sudden onset of disease.)
GAU:	Covered by DSHS
Medicare Advantage:	Covered benefit. Use CMS NCDs & must be performed in a Medicare-approved facility

3. Required Approvals:

Transplant services require prior authorization by the Plan Medical Director or her/his designee.

4. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- 2006-2007 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

33 Transplant – Single and Bilateral Lung

Subject: Transplant – Single and Bilateral Lung	
<input type="checkbox"/> Original	Original Committee Approval: November 5, 1997
<input checked="" type="checkbox"/> Revised	Last Committee Approval: January 4, 2006
	Last Review: October 2006

NOTE: Interlink criteria are used to review transplant-related requests.

1. Background:

This service requires a referral to Community Health Plan’s Case Management Department.

2. Retransplantation:

Same as for initial transplant.

3. Limitations/Exclusions:

Healthy Options:	Covered benefit.
PEBB:	Covered benefit.
Basic Health Plan:	Transplant services may be covered after 12-month waiting period. (This may be waived for newborns or sudden onset of disease.)
GAU:	Covered by DSHS
Medicare Advantage:	Covered benefit. Use CMS NCDs & must be performed in a Medicare-approved facility

4. Required Approvals:

Transplant services require prior authorization by the Plan Medical Director or her/his designee.

5. References:

- Interlink 2005-2006 Transplant Criteria™.
- Supplemental: Milliman Transplant Criteria and Chronic Care Management Guidelines.
- 2006 Healthy Options Contract.
- 2007 Basic Health Contract.
- 2007 PEBB Certificate of Coverage.
- 2006-2007 GAU Contract.
- 2007 Medicare Advantage Contract.

34 TYSABRI™ (natalizumab)

Subject: TYSABRI™ - (natalizumab)	
<input checked="" type="checkbox"/> Original	Original P&T Committee Approval: October 13, 2006
<input type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 13, 2006

1. Background:

Tysabri™, a monoclonal antibody that blocks the effects of $\alpha 4$ integrin and thus the infiltration of T-lymphocytes across the blood brain barrier, is approved by the Food and Drug Administration (FDA) for the treatment of patients with relapsing forms of multiple sclerosis (MS) to delay the accumulation of physical disability and reduce the frequency of clinical exacerbations.^{xxiii} Tysabri™ is generally reserved for MS patients who have had an inadequate response to, or are unable to tolerate other MS therapies, because it increases the risk of progressive multifocal leukoencephalopathy (PML), an opportunistic viral infection of the brain that usually leads to death or severe disability. The recommended dose is 300 mg by an intravenous (IV) infusion in 100 mL 0.9% sodium chloride over approximately one hour, every 4 weeks.

Tysabri™ was initially approved by the FDA to treat relapsing forms of MS in November 2004, but was withdrawn by the manufacturer in February 2005, because three patients in clinical trials developed PML.^{xxiv} The cases of PML have been described in published reports.^{xxv, xxvi, xxvii} In March 2006, an FDA advisory committee recommended a risk-minimization program for Tysabri™. Thus, Tysabri™ is available only through registered infusion centers that are enrolled in the TOUCH™ Prescribing Program, which includes participation by the prescriber, patient, pharmacy and infusion center. The FDA revised Tysabri™'s indication to limit its use to monotherapy, because it is unknown how its use with other immune modifying drugs could impact its safety.

Tysabri™'s efficacy in MS was assessed in two pivotal, 2-year, randomized, double-blind, placebo-controlled studies.^{xxviii, xxix} Both trials included MS patients who had at least one clinical relapse during the prior year and had a Kurtzke Expanded Disability Status Scale (EDSS) score between 0 and 5.0. Neurological evaluations were performed every 12 weeks and at the time of suspected relapse. Magnetic resonance imaging (MRI) evaluations, including evaluations for T1-weighted gadolinium (Gd)-enhancing lesions and T2-hyperintense lesions, were also done

annually. In both trials, the primary endpoint at 2 years was the time to onset of sustained increase in disability, defined as a ≥ 1.0 point increase on the EDSS from baseline EDSS ≥ 1.0 that was sustained for 12 weeks, or a ≥ 1.5 point increase on the EDSS from baseline EDSS = 0 that was sustained for 12 weeks.

In the first pivotal trial, patients had not received any interferon beta or glatiramer acetate for at least the previous 6 months and most patients (94%) had never received these agents. In a 2:1 ratio, patients were randomized to receive Tysabri™ 300 mg IV (n = 627) or placebo (n = 315) every 4 weeks for up to 28 months. The median patient age and disease duration were 36 years and 5 years, respectively. Sixty-seven percent of patients had EDSS scores ≤ 2.5 . After 2 years of follow-up there was a 67% relative reduction in the annualized relapse rate for those given Tysabri™ (P < 0.001) (annualized relapse rates were 0.22 for Tysabri™ vs. 0.67 for placebo). A greater percentage of patients given Tysabri™ were relapse-free (67%) compared with placebo (41%) at two years (P < 0.001). MRI endpoints were favorable with Tysabri™ as the number of new or enlarging hyperintense lesions detected by T2-weighted MRI over two years was reduced by 83% as compared with placebo (P < 0.001). Over two years, no new or enlarging hyperintense lesions developed in 57% of patients in the Tysabri™ group compared with 15% given placebo (P < 0.001). A reduced percentage given Tysabri™ displayed 3 or more new or enlarging hyperintense lesions (18%) compared with placebo (68%) (P < 0.001). Lesions detected by Gd-enhanced MRI were absent in 97% of patients given Tysabri™ compared with 72% in the placebo group at two years (P < 0.001).

In the second pivotal trial, MS patients who had experienced one or more relapses while receiving interferon beta-1a (Avonex™) 30 mcg intramuscularly (IM) once weekly (QW) during the year prior were randomized to receive Tysabri™ 300 mg IV (n = 589) or placebo (n = 582) every 4 weeks for up to 28 months, while continuing therapy with interferon beta-1a. The median patient age was 39 years and the median disease duration was 7 years. Sixty-five percent of patients had EDSS scores ≤ 2.5 . This study was halted one month early due to two reports of PML. After a median follow-up of 2 years, use of Tysabri™ with interferon beta-1a led to a 56% relative reduction in the annualized relapse rate compared with placebo plus interferon beta-1a (0.33 vs. 0.75; P < 0.001). The percentage of patients who remained relapse-free was greater for those given Tysabri™ plus interferon beta-1a (54%) compared with placebo plus interferon beta-1a (32%) (P < 0.001). MRI data was also positive for Tysabri™ in that after 2 years, the percentage of patients with no new or newly enlarging T2-hyperintense lesions was greater for those given Tysabri™ plus interferon beta-1a (67%) compared with placebo plus interferon beta-1a (30%) (P < 0.001). The percentage with no new or newly enlarging Gd-enhancing lesions was 96% and 75%, respectively (P < 0.001). The number of new

or enlarging T2-hyperintense lesions over the two years was reduced by 83% with combination therapy (P < 0.001).

Immunomodulator therapy, which should be considered for use as soon as possible after a definite diagnosis of MS, include interferon beta-1b (Betaseron™), interferon beta-1a (Avonex™, Rebif™) and glatiramer acetate (Copaxone™).^{xxx, xxxi} These agents have demonstrated an approximate 30% reduction in the exacerbation rate (relapse rate) in pivotal trials lasting 2-3 years. Noted adverse effects with the interferon beta products include an increased risk of depression, flu-like symptoms, seizures, and injection site reactions.^{xxxii, xxxiii, xxxiv} Glatiramer acetate is mainly associated with injection site reactions, and an immediate post-injection reaction which involves symptoms such as flushing, chest pain, and constriction of the throat.^{xxxv} The side effect profile of Tysabri™ is different from the other immunomodulating products with hypersensitivity reactions, infusion-related reactions, immunosuppression that leads to an increased risk of infections, and rare cases of PML being notable. The administration regimen also varies with these products. Glatiramer acetate is given subcutaneously (SC) daily, interferon beta-1b is administered SC every other day, interferon beta-1a (Rebif™) is given SC three time per week, and interferon beta-1a (Avonex™) is given IM once weekly. These products are self-administered, whereas Tysabri™ is an IV infusion given every 4 weeks.

2. Indications/Criteria:

The use of Tysabri™ may be considered medically necessary in patients (age > 18 years) meeting all of the following criteria:

- Diagnosis of relapsing forms of MS,
- Prescribed by a neurologist or an MS-specialist who is registered with the TOUCH™ prescribing program,
- Previous trial and failure with an immunomodulator (e.g., Avonex™, Betaseron™, Copaxone™, or Rebif™),
- Patient’s therapeutic plan does not include concurrent therapy with an immunomodulator, and
- Dosing should not exceed 300 mg every four weeks.

The use of Tysabri™ will be considered investigational when used in combination with another immunomodulator, in MS patients with chronic progressive MS, in ulcerative colitis or Crohn’s disease patients, and/or other pathological indications.

3. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.

GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

4. Required Review and Approvals:

Tysabri™ infusions require prior authorization by the CHP Medical Director or his/her designee. Each authorization period will be for six months.

5. References:

^{xxiii} Tysabri® [package insert]. San Diego (CA): Biogen Idec, Inc;2006 Jun.

^{xxiv} U.S. Food and Drug Administration. Natalizumab (marketed as Tysabri®) information. [Online]. 2006 Jun 14 [cited 2006 Jun 15]. Available from:
URL:<http://www.fda.gov/cder/drug/infopage/natalizumab/default.htm>

^{xxv} Langer-Gould A, Atlas SW, Green AJ, et al. Progressive multifocal leukoencephalopathy in a patient treated with natalizumab. N Engl J Med 2005;353(4):375-381.

^{xxvi} Kleinschmidt-DeMasters BK, Tyler KL. Progressive multifocal leukoencephalopathy complicating treatment with natalizumab and interferon beta-1a for multiple sclerosis. N Engl J Med 2005;353(4):369-374.

^{xxvii} Van Assche G, Ranst MV, Sciôt R, et al. Progressive multifocal leukoencephalopathy after natalizumab therapy for Crohn's disease. N Engl J Med 2005;353(4):362-8.

^{xxviii} Polman CH, O'Connor PW, Havrdova E, et al, for the AFFIRM Investigators. A randomized, placebo-controlled trial of natalizumab for relapsing multiple sclerosis. N Engl J Med 2006;354(6):899-910.

^{xxix} Rudick RA, Stuart WH, Calabresi PA, et al, for the SENTINEL Investigators. Natalizumab plus interferon beta-1a for relapsing multiple sclerosis. N Engl J Med 2006;354(9):911-923.

^{xxx} Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology 2002;58(2):169-178.

^{xxxi} National Multiple Sclerosis Society. Expert Opinion Paper. Medical Advisory Board of the National Multiple Sclerosis Society. Treatment Recommendations for Physicians. Disease Management Consensus Statement. [Online]. [cited 2005 Jun 15]. Available at
URL:http://www.nationalmssociety.org/pdf/forpros/Exp_Consensus.pdf.

^{xxxi} Avonex® [package insert]. Cambridge (MA): Biogen Idec, Inc; 2006 May.

^{xxxiii} Betaseron® [package insert]. Montville (NJ): Berlex Laboratories; 2003 Oct.

^{xxxiv} Rebif® [package insert]. Rockland (MA): Serono, Inc; 2005 Sep.

^{xxxv} Copaxone® [package insert]. Teva Neuroscience, Inc; 2004 Feb.

35 Ventilators

Subject: Ventilators	
<input type="checkbox"/> Original	Original Committee Approval:
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

This service requires a referral to Community Health Plan's Case Management Department. Milliman CareGuidelines and CHP Case Management Longterm Acute Desk Procedure 2006 are used for Medical Review.

36 Viscosupplementation

Subject: Viscosupplementation (Sodium Hyaluronate / Hyaluronan): Synvisc™, Hyalgan™, Orthovisc™, Supartz™, Hylan GF-20 Injections	
<input type="checkbox"/> Original <input checked="" type="checkbox"/> Revised	Original Committee Approval: February 8, 2002
	Last Committee Approval: December 20, 2006
	Last Review: October 2006

1. Background:

Sodium hyaluronate, or hyaluronan, is a naturally occurring viscoelastic fluid that provides lubrication and protection for the knee joint. Synthetic preparations of this fluid such as Synvisc and Hylan GF-20 (Hyalgan) have been approved by the FDA to treat osteoarthritis of the knee in selected patients. In a procedure known as viscosupplementation, these substances are injected into the knee joint. The therapeutic goal of such an intervention is to improve mobility and alleviate pain.

2. Indications/Criteria:

Patients must have all of the following:

- Documented symptomatic osteoarthritis or chondromalacia of the knee,
- Pain which interferes with activities of daily living (e.g., prolonged standing, ambulation),
- Failure to respond to conservative nonpharmacologic therapy (i.e., physical therapy, documented attempts at weight loss, and exercise) over a six-month course (minimum),
- Failure to respond to nonprescription analgesics,
- Failure to respond to at least 2 prescription NSAIDs, and
- Failure to respond to a trial of intra-articular steroid injections (unless medically contraindicated).

Retreatment Criteria:

- Documented improvement in function and pain,
- Documented significantly reduced doses of NSAIDs or non-prescription analgesics, and
- A minimum of 6 months since last Sodium Hyaluronate injection.

3. Limitations/Exclusions:

Healthy Options:	None; pre-authorization required.
PEBB:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

4. Required Review and Approvals:

Sodium Hyaluronate and similar viscosupplementation products require prior authorization by the CHP Medical Director or his/her designee.

5. References:

- Hayes Inc. Online 2006.
- Milliman Care guidelines 2006.
- Lo GH, LaValley M, et al. Intra-articular hyaluronic acid in the treatment of knee osteoarthritis: a meta analysis. JAMA 2003;290:3115-21.
- Felson DT, et al. Hyaluronate sodium injections for osteoarthritis. Arch Intern Med 2002;162:245-7.
- Premera. Intra-articular hyaluronan injections for osteoarthritis of the knee. Premera Corporate Medical Policy 2006 Jun 16;(5.01.506).

37 Wheelchairs

Subject: Wheelchairs	
<input type="checkbox"/> Original <input checked="" type="checkbox"/> Revised	Original Committee Approval: February 8, 2002 Last Committee Approval: December 20, 2006
	Last Review: October 2006

Clinical guidelines changed from CHP Criteria to Milliman CareGuidelines.

38 Xolair™ (Omalizumab) Injections

Subject: Xolair™ (Omalizumab) Injections	
<input type="checkbox"/> Original	Original Committee Approval: August 27, 2003
<input checked="" type="checkbox"/> Revised	Last Committee Approval: December 20, 2006
	Last Review: October 2006

Clinical guidelines changed from CHP Criteria to Milliman CareGuidelines.