Utilization Management (UM) Criteria for Hyperbaric Oxygen (HBO) / Systemic, Medi-Cal, Including Members Under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit Under the Age of 21

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Utilization Management Criteria Statement

This document includes criteria that supports utilization review of certain provider requested health care services. Refer to the NCAL UM Criteria List.

Utilization review occurs when a qualified physician other than the treating clinician reviews the treating clinician's request against utilization review criteria. The qualified physician is in the position to approve, deny, delay or modify the service request based on a determination of medical necessity. These criteria are consistent with professional standards of practice and provided for your reference.

If you are in a treatment relationship with a member your clinical recommendations are not subject to these criteria. Your treatment recommendations are guided by your professional judgment and influenced, where applicable, by clinical practice guidelines and clinical support tools found in the Library under "Guidelines".

Principles

Kaiser Foundation Health Plan provides Hyperbaric Oxygen therapy to members who have medical conditions that scientific literature shows respond to HBO therapy, and which have not responded to conventional treatments, if it is determined that HBO may be of benefit.

It increases the concentration of dissolved oxygen in the blood, which enhances perfusion. HBO therapy provides a therapeutic dose of oxygen by creating a pressurized environment in which patients intermittently breathe 100 percent oxygen at pressures greater than normal atmospheric (sea level) pressure. This procedure was originally developed for the treatment of decompression sickness, but the primary usage in the United States currently is for wound care. Although the mechanisms of action for hyperbaric oxygen's therapeutic effects are not firmly established in scientific literature, it is generally agreed that HBO therapy serves four primary functions:

- 1. It increases the concentration of dissolved oxygen in the blood, which enhances perfusion.
- 2. It stimulates the formation of a collagen matrix so that new blood vessels may develop (angiogenesis).
- 3. It replaces inert gas (such as nitrogen) in the bloodstream with oxygen, which the body is able to metabolize.
- 4. It works as a bactericide.

Kaiser Foundation Health Plan, Inc. covers Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services, as required by law for Medi-Cal Managed Care Plan (MCP) members under 21, when determined to be medically necessary based upon the standards set forth in federal Medicaid law for EPSDT (Title 42 of the USC Section 1396(r)(6)) and the member's current clinical condition. The EPSDT medically necessity criteria indicate services must be covered to correct or ameliorate defects and physical and mental illnesses or conditions. Services must also be provided when medically necessary to prevent disease, disability, and other health conditions or their progression, to prolong life, and to promote physical and mental health and efficiency.

Service/s need not cure a condition in order to be covered under EPSDT. Services that maintain or improve the child's current health condition are also covered under EPSDT because they "ameliorate" a condition. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. The common definition of "ameliorate" is to "make more tolerable." Additional services must be provided if determined to be medically necessary for an individual child.

Medical necessity decisions are individualized. Flat limits or hard limits based on a monetary cap or budgetary constraints are not consistent with EPSDT requirements. Therefore, MCPs are prohibited from imposing service limitations on any EPSDT benefit other than medical necessity. The determination of whether a service is

Clinical Review Criteria

TPMG recognizes the evidence-based role of HBO therapy in patients with indications as outlined in Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations Manual, Chapter 1, Section 20.29 for HBO therapy. These indications are as follows:

- 1. Acute carbon monoxide intoxication
- 2. Decompression illness
- 3. Gas embolism

- 4. Gas gangrene
- 5. Acute traumatic peripheral ischemia when loss of function, limb, or life is threatened
- 6. Crush injuries and suturing of severed limbs when loss of function, limb, or life is threatened
- 7. Progressive necrotizing infections
- 8. Acute peripheral arterial insufficiency
- 9. Preparation and preservation of compromised skin grafts (not for primary management of wounds)
- 10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management
- 11. Wound healing of a non-healing mastectomy site
- 12. Moderate to severe chronic radiation cystitis refractory to conservative treatment
- 13. Soft tissue radionecrosis
- 14. Prevention of Osteoradionecrosis of the jaw including prior to and after dental extractions post-radiation therapy.
- 15. Cyanide poisoning
- 16. Actinomycosis when refractory to antibiotics and surgical treatment
- 17. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
 - o Patient has Type I or Type II Diabetes and has a lower extremity wound that is due to Diabetes.
 - o Patient has a wound classified as Wagner Grade III or higher; and
 - o Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care.

Standard wound care in patients with Diabetic wounds includes:

- Assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible,
- o Optimization of nutritional status,
- o Optimization of glucose control,
- Debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off/loading, and
- Necessary treatment to resolve any infection that might be present.

Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30/day period of treatment.

NOTE: Topical application of oxygen does not meet the definition of HBO therapy and is considered investigational/not medically necessary in all cases. Also, its clinical efficacy has not been established.

- 18. Osteoradionecrosis (ORN) treatment:
 - o If *established* ORN: patients will require 30 pre-extraction or pre-surgical treatments and then 10 post extraction/surgery treatments.
 - o If *at risk* for ORN: patients will require 20 pre-extraction or pre-surgical treatments and then 10 post extraction/surgery treatments.
 - o If *treated for ORN or prophylaxis for ORN* with either a 30/10 or 20/10 protocol within the past 3-years, they will only require 10 post extraction/post-surgical treatments for additional procedures.
- 19. Central Retinal Artery Occlusion when treatment initiated within 24/hours
- 20. Sudden Sensorineural Hearing Loss

Presentation of Mild to Moderate Hearing Drop:

Oral and Intratympanic (IT) steroid therapy should be discussed with all patients.

Treatment

- o Should be initiated, if possible, within 2 weeks of onset.
- o Oral steroid alone should be recommended as initial therapy for mild to moderate HL within 2 weeks of onset but can be offered up to 6 weeks after onset.
- o IT steroid should be strongly recommended as initial therapy if there are medical contraindications to oral steroid and as salvage therapy for oral steroid failure within 6 weeks of onset.
- Combo therapy (oral and IT steroid) should be recommended for those presenting more than 2 weeks after onset and within 6 weeks of onset. Combo therapy (oral and IT steroid) can be offered as initial therapy within 6 weeks of onset if preferred by the patient.

HBO should not be offered unless there are medical contraindications to oral and/or IT steroid therapy or special situations i.e. salvage in only hearing ear. Patients with > 25% drop in discrimination regardless of the severity of their pure tone loss should be treated as presenting with severe to profound HL patients

Presentation of Severe to Profound Hearing Drop:

- Oral and IT steroid therapy should be discussed with all patients. Treatment should be initiated if possible, within 2 weeks of onset.
- Combo therapy (oral and IT steroid) should be "strongly" considered within 6 weeks of onset. IT steroid should be strongly recommended as therapy if there are medical contraindications to oral steroid within 6 weeks of onset.

HBO should not be considered routinely as adjuvant initial or adjuvant salvage therapy unless there are medical contraindications to oral or IT steroid therapy or special situations i.e. salvage in only hearing ear.

Providers should strongly recommend against HBO as **isolated** initial or salvage therapy unless there are absolute medical contraindications to oral and/or IT steroid therapy.

Treatment

- o Oral Prednisone should be 60mg daily for at least 7 days.
- o IT steroids should be Dexamethasone 10mg/ml up to 3 injections as needed.
- o Treatment intervals "weekly" HBO: 100% at 2-2.5 ATA 10-20 Dives lasting 90 or 60 minutes.
- Must be initiated within 2 weeks of onset when considering as initial adjuvant therapy and must be initiated within 4 weeks of onset when considering as salvage adjuvant therapy.

Audiogram:

- o **Initial:** After initiation of treatment: consider audiograms prior to additional interventions or if patient reports significant improvement
- o **Post-Intervention:** After the last intervention, 6 months after last intervention.

Ruling out Retro-cochlear Lesion:

- o MRI recommended to rule out IAC lesion.
- o If there are contra-indications to MRI then CT is preferred modality.

Routine Laboratory Testing:

o Not recommended

Non-covered Conditions

The following indications are excluded from coverage:

- Cutaneous, decubitus and stasis ulcers
- Chronic peripheral vascular insufficiency
- Anaerobic septicemia and infection, other than clostridial
- Skin burns (thermal)
- Senility
- Myocardial infarction
- Cardiogenic shock
- Sickle cell anemia
- Acute thermal and chemical pulmonary damage, i.e., smoke inhalation and pulmonary insufficiency
- Acute or chronic cerebral vascular insufficiency
- Hepatic necrosis
- Aerobic septicemia

- Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease)
- Tetanus
- Systemic aerobic infection
- Organ transplantation
- Organ storage
- Pulmonary emphysema
- Exceptional blood loss anemia
- Multiple sclerosis
- Arthritic diseases
- Acute cerebral edema

Contributors/Clinical Experts

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Approving Bodies

Chiefs of Radiation Oncology	6/19/08, 7/14/09, 7/20/10, 6/9/11, 6/18/12, 7/17/13, 7/8/14, 7/23/15, Electronic, 8/15/18, 8/17/2021 Electronic, 04/19/2022 Electronic
Chiefs of Surgery	7/20/10, 6/9/11, 7/23/13, 7/8/14, 7/29/15, Electronic, 8/14/18, 8/17/2021 Electronic, 05/09/2022 Electronic, 08/15/2023, 05/07/2024
Chiefs of Neurology	5/28/10, 6/11/11, 7/22/13, 7/7/14, 7/20/15, Electronic, 8/14/18, 8/17/2021 Electronic,05/09/2022 Electronic, 08/15/2023, 06/11/2024
APICs for Outside Services	11/29/06, 11/14/07, 7/23/08, 7/22/09, 7/21/10, 7/20/11, 7/25/12, 7/24/13, 7/23/14, 7/29/15, 8/23/17, 8/22/18, 8/28/19, 8/26/20, Electronic-2021 XX/XX 2024
Resource Management Committee (RMC)	9/5/12, 7/30/13, 9/24/13, 7/29/14 7/28/15, 9/27/16, 8/22/17, 8/28/18 9/24/19, 8/25/20, 8/24/2021, 05/24/2022, 08/22/2023, 07/23/2024
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