Hyperbaric Oxygen Therapy

Hyperbaric oxygen therapy (HBOT) is a technique of delivering higher pressures of oxygen to the tissues. Two methods of administration are available: systemic and topical.

In systemic or large hyperbaric oxygen chambers, the patient is entirely enclosed in a pressure chamber and breathes oxygen at a pressure greater than 1 atmosphere (the pressure of oxygen at sea level). Thus, this technique relies on systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic hyperbaric oxygen therapy can be used to treat systemic illness, such as air or gas embolism, carbon monoxide poisoning, clostridial gas gangrene, etc. Treatment may be carried out either in a monoplace chamber pressurized with pure oxygen or in a larger, multiplace chamber pressurized with compressed air, in which case the patient receives pure oxygen by mask, head tent, or endotracheal tube.

Topical hyperbaric oxygen therapy is a technique of delivering 100% oxygen directly to an open, moist wound at a pressure slightly higher than atmospheric pressure. It is hypothesized that the high concentrations of oxygen diffuse directly into the wound to increase the local cellular oxygen tension, which in turn promotes wound healing. Topical hyperbaric oxygen devices consist of an appliance to enclose the wound area (frequently an extremity) and a source of oxygen; conventional oxygen tanks may be used. The appliances may be disposable and may be used without supervision in the home by well-trained patients. Topical hyperbaric oxygen therapy has been investigated as a treatment of skin ulcerations resulting from diabetes, venous stasis, postsurgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, burns, or frostbite.

HBOT is a generally safe therapy, with an estimated adverse side effect of 0.4%. Adverse events may occur either from pressure effects or the oxygen. The pressure effect (barotrauma) may affect any closed air-filled cavity such as ears, sinus, teeth, and lungs. Pain and/or swelling may occur at these sites as pressure increases during the procedure, and decreases as the procedure is ending. Oxygen toxicity may affect the pulmonary, neurologic, or ophthalmologic systems. Pulmonary symptoms include a mild cough, substernal burning, and dyspnea. Neurologic effects include tunnel vision, tinnitus, nausea and dizziness. Ophthalmologic effects include retinopathy in neonates, cataract formation and transient myopic vision changes.

Regulatory Status
In 2013, FDA published a statement warning that non-FDA approved uses of HBOT may endanger the health of patients. If patients mistakenly believe that HBOT devices have been proven safe for uses not cleared by FDA, they may delay or forgo proven medical therapies.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.
**Hyperbaric Oxygen Therapy**

**Policy**

BCBSNC will cover Hyperbaric Oxygen Therapy treatment when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

*Topical Hyperbaric Oxygen Therapy is considered investigational. BCBSNC does not cover investigational services.*

**Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member’s Benefit Booklet for availability of benefits. Member’s benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**When hyperbaric oxygen therapy is covered**

Systemic hyperbaric oxygen therapy may be considered medically necessary in the treatment of the following conditions:

1. non-healing diabetic wounds of the lower extremities in patients who:
   - have type I or type II diabetes and a lower extremity wound due to diabetes,
   - have a wound classified as Wagner grade 3 or higher*; and
   - have no measurable signs of healing after 30 days of an adequate course of standard wound therapy

2. acute traumatic ischemia e.g. crush injuries, reperfusion injury, compartment syndrome;

3. decompression sickness

4. air or gas embolism, acute

5. cyanide poisoning, acute

6. carbon monoxide poisoning

7. soft-tissue radiation necrosis (e.g., radiation enteritis, cystitis, proctitis) and osteoradionecrosis

8. pre-treatment and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw

9. gas gangrene (clostridial myonecrosis)

10. profound anemia with exceptional blood loss: only when blood transfusion is impossible or must be delayed

11. chronic refractory osteomyelitis

12. compromised skin grafts or flaps

13. necrotizing soft-tissue infections

14. moderate to profound idiopathic sudden sensorineural hearing loss, when treatment is within three months of diagnosis

15. intracranial abscesses

16. acute thermal burns

17. arterial insufficiencies:
   - central retinal artery occlusion, or
   - enhancement of healing in selected problem wounds

* The Wagner classification system of wounds is defined as follows: grade 0=no open lesion; grade 1=superficial ulcer without penetration to deeper layers; grade 2=ulcer penetrates to tendon, bone or joint; grade 3=lesion has penetrated deeper than grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths; grade 4=wet or dry gangrene in the toes or forefoot; grade 5=gangrene involves the whole foot or such a percentage that no local procedures are possible and amputation (at least at the below the knee level) is indicated.
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When hyperbaric oxygen therapy is not covered

Hyperbaric oxygen therapy is considered investigational in the treatment of all other conditions, except those listed above as covered.

Policy Guidelines

In 2014, the Undersea and Hyperbaric Medical Society (UHMS) updated their list of indications considered appropriate for HBOT. These indications are as follows:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide complicated by cyanide poisoning
3. Clostridial myositis and myonecrosis (gas gangrene)
4. Crush injury, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness
6. Arterial insufficiencies
   - Central retinal artery occlusion
   - Enhancement of healing in selected problem wounds
7. Severe anemia
8. Intracranial abscess
9. Necrotizing soft tissue infections
10. Osteomyelitis (refractory)
11. Delayed radiation injury (soft tissue and bony necrosis)
12. Skin grafts and flaps (compromised)
13. Acute thermal burn injury
14. Idiopathic sudden sensorineural hearing loss (ISSNHL) (patients with moderate to profound ISSNHL)

UHMS has also published position statements that concluded there was insufficient evidence to recommend topical HBOT for chronic wounds, multiple sclerosis, and autism spectrum disorder.

Summary of Evidence

For individuals with wounds, burns or infections who receive topical HBOT, the evidence includes a systematic review, case series, and an RCT. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. The systematic review identified 3 RCTs including patients with sacral pressure ulcers, ischial pressure ulcers, and refractory venous ulcers. All trials reported that healing improved significantly after HBOT than after standard of care. Pooling of results was not possible due to heterogeneity in patient populations and treatment regimens. The single small RCT (N=28) was not included in the review and the uncontrolled studies do not provide sufficient data that topical HBOT is efficacious. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic diabetic ulcers who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms and change in disease status. Meta-analyses of RCTs found significantly higher diabetic ulcer healing rates with HBOT than with control conditions. One of the 2 meta-analyses found that HBOT was associated with a significantly lower rate of major amputation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with carbon monoxide poisoning who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival and symptoms. A meta-analysis in a Cochrane review of low-quality RCT data did not find HBOT to be associated
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with a significantly lower risk of neurologic deficits after carbon monoxide poisoning. The
evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with radionecrosis, osteoradionecrosis, or treatment of irradiated jaw who receive
systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are
symptoms and change in disease status. A meta-analysis in a Cochrane review of RCTs found
evidence that HBOT improved radionecrosis and osteoradionecrosis outcomes and resulted in
better outcomes before tooth extraction in an irradiated jaw. The evidence is sufficient to
determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with chronic refractory osteomyelitis who receive systemic HBOT, the evidence
includes case series. Relevant outcomes are symptoms and change in disease status. The case
series reported high rates of successful outcomes (no drainage, pain, tenderness, or cellulitis) in
patients with chronic refractory osteomyelitis treated with HBOT. However, controlled studies
are needed to determine conclusively the impact of HBOT on health outcomes compared with
other interventions. The evidence is insufficient to determine the effects of the technology on
health outcomes.

For individuals with acute surgical and traumatic wounds who receive systemic HBOT, the
evidence includes RCTs, controlled nonrandomized studies, and systematic reviews. Relevant
outcomes are overall survival, symptoms, and change in disease status. There was considerable heterogeneity across the 4 RCTs identified (eg, patient population, comparison group, treatment regimen, outcomes). This heterogeneity prevented pooling of trial findings and limits the ability to conclude the impact of HBOT on health outcomes for patients with acute surgical and traumatic wounds. Additional evidence from high-quality RCTs is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with acute thermal burns who receive systemic HBOT, the evidence includes a
systematic review of 2 RCTs. Relevant outcomes are overall survival, symptoms, and change in
disease status. Only 2 RCTs were identified, and both were judged to have poor methodologic
quality. Evidence from well conducted controlled trials is needed. The evidence is insufficient to
determine the effects of the technology on health outcomes.

For individuals with bisphosphonate-related osteonecrosis of the jaw who receive systemic
HBOT, the evidence includes an RCT. Relevant outcomes are symptoms and change in disease
status. The RCT was unblinded and reported initial benefits at 3-month follow-up; however, there
were no significant benefits of HBOT for most health outcomes compared with standard care in
the long-term (6 months to 2 years). The evidence is insufficient to determine the effects of the
technology on health outcomes.

For individuals with necrotizing soft tissue infections who receive systemic HBOT, the evidence
includes systematic reviews and a retrospective cohort study. Relevant outcomes are overall
survival, symptoms, and change in disease status. A Cochrane review did not identify any RCTs.
Another systematic review identified a retrospective cohort study, which did not find better
outcomes after HBOT than after standard care without HBOT in patients with necrotizing soft
tissue infections. The evidence is insufficient to determine the effects of the technology on health
outcomes.

For individuals with acute coronary syndrome who receive systemic HBOT, the evidence
includes RCTs and a systematic review. Relevant outcomes are overall survival, symptoms,
change in disease status, and functional outcomes. A Cochrane review identified 6 RCTs. There
were 2 pooled analyses, one found significantly lower rates of death with HBOT and the other
reported inconsistent results in left ventricular function. Additional RCT data are needed. The
evidence is insufficient to determine the effects of the technology on health outcomes.
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For individuals with acute ischemic stroke who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. Cochrane reviewers could only pool data for a single outcome (mortality at 3-6 months), and for that outcome, there was no significant difference between active and sham HBOT treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with motor dysfunction associated with stroke who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms and functional outcomes. The RCT, which used a crossover design, found better outcomes with HBOT at 2 months than with delayed treatment. However, the trial had a number of methodologic limitations (eg, lack of patient blinding, heterogeneous population, high dropout rate) that make it difficult to evaluate the efficacy of HBOT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with Bell palsy who receive systemic HBOT, the evidence includes a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A Cochrane review did not identify any RCTs meeting selection criteria; the single RCT found did not have a blinded outcome assessment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with traumatic brain injury who receive systemic HBOT, the evidence includes RCTs and systematic reviews. Relevant outcomes are overall survival, symptoms, change in disease status, and functional outcomes. RCTs were heterogeneous regarding intervention protocols, patient populations, and outcomes reported. Systematic reviews conducted pooled analyses only on a minority of the published RCTs, and these findings were inconsistent. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with inflammatory bowel disease who receive systemic HBOT, the evidence includes an RCT, observational studies, and a systematic review. Relevant outcomes are symptoms, change in disease status and functional outcomes. One small RCT has been published, and this trial did not find a significant improvement in health outcomes when HBOT was added to standard medical therapy. A systematic review including the RCT and observational studies found a high rate of bias in the literature due to attrition and reporting bias. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with idiopathic sudden sensorineural hearing loss who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A Cochrane review with pooled analysis of 2 RCTs did not find a statistically significant difference in outcomes between the HBOT and the control groups in hearing for all frequencies at a level greater than 50%, but did find a statistical difference at a level greater than 25%. An RCT published after the review reported no differences in hearing between groups at 4 different frequencies. The RCTs had methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with delayed-onset muscle soreness who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs found worse short-term pain outcomes with HBOT than with control and no difference in longer term pain or other outcomes (eg, swelling). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with autism spectrum disorder who receive systemic HBOT, the evidence includes an RCT and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review identified a single RCT on HBOT for autism spectrum disorder and this trial did not find significantly better parental-assessed or clinician-assessed outcomes.
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with HBOT compared with sham. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cerebral palsy who receive systemic HBOT, the evidence includes 2 RCTs and an observational study. Relevant outcomes are symptoms and functional outcomes. One RCT was stopped early due to futility, and the other did not find significantly better outcomes with HBOT than with a sham intervention. The observational study focused on sleep disorders in children with cerebral palsy and reported improvements with the HBOT treatment. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with vascular dementia who receive systemic HBOT, the evidence includes an RCT and a systematic review. Relevant outcomes are symptoms and functional outcomes. The Cochrane review identified only a single RCT with methodologic limitations. Well-conducted controlled trials are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with radiotherapy adverse events who receive systemic HBOT, the evidence includes RCTs, nonrandomized comparator trials, case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Two systematic reviews were identified, but pooled analyses were not possible due to heterogeneity in treatment regimens and outcomes measured. One systematic review concluded that more RCTs would be needed. The 2 RCTs identified had inconsistent findings. One reported no short-term benefit with HBOT, but some benefits 12 months after radiotherapy; the other did not find a significant benefit of HBOT at 12-month follow-up. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with idiopathic femoral neck necrosis who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The RCT, which had a small sample, only reported short-term (ie, 6-week) outcomes. Larger well-conducted RCTs reporting longer term outcomes are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with a migraine who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The Cochrane review conducted a pooled analysis including 3 of the 11 trials. Meta-analysis of these 3 RCTs found significantly greater relief of migraine symptoms with HBOT than with a comparator intervention within 45 minutes of treatment. Longer term data are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with herpes zoster who receive systemic HBOT, the evidence includes an RCT. Relevant outcomes are symptoms and change in disease status. The RCT was unblinded and only reported short-term (ie, 6-week) outcomes. Additional well-conducted RCTs with longer follow-up are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with fibromyalgia who receive systemic HBOT, the evidence includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Only 2 RCTs were identified, and both reported positive effects of HBOT on tender points and pain. However, the trials had relatively small samples and methodologic limitations (eg, quasi-randomization, no or uncertain sham control for a condition with subjective outcomes susceptible to a placebo effect). Moreover, the HBOT protocols varied. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with multiple sclerosis who receive systemic HBOT, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and functional outcomes. A Cochrane review of RCTs did not find a significant difference in Expanded Disability Status Scale scores.
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when patients with multiple sclerosis were treated with HBOT vs a comparator intervention. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with cancer and are undergoing chemotherapy who receive systemic HBOT, the evidence includes an RCT and a systematic review. Relevant outcomes are overall survival and change in disease status. While the systematic review reported improvements in tumor control in patients with head and neck cancer who received HBOT, the adverse events accompanying the treatment (eg, radiation tissue injury, seizures) were significant. The single RCT did not find a significant difference in survival for cancer patients who received HBOT before chemotherapy compared with usual care. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 99183, A4575, E0446, G0277

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

For policy titled “Hyperbaric Oxygen Pressurization”


TEC Assessment - 10/20/99


Hyperbaric Oxygen Therapy


Senior Medical Director- December 2014


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For policy titled, “Hyperbaric Oxygen Therapy”


Medical Director 1/ 2016


Policy Implementation/Update Information

For policy titled, “Hyperbaric Oxygen Pressurization”

4/80 Original policy


6/84 Reaffirmed.

8/92 Revised

4/96 Revised: Combined local and national policies. Added indication for patients who have undergone radiation to the head and neck requiring full mouth extraction. Investigation diagnosis for prophylactic Hyperbaric Oxygen following radiation therapy added.

4/97 Reaffirmed

3/99 Revised: Added statement that topical hyperbaric oxygen therapy is considered investigational. Reaffirmed by MPAG.

5/99 Reformatted, Procedural description changed, Medical Term Definitions added.


5/00 Revised: Indications changed per update from the BCBSA, TEC review, and Independent Consultant recommendations. Compromised skin grafts or flaps and acute thermal burns are non-covered indications.

6/00 Medical Policy Advisory Group 7/00 System coding changes

9/01 Medical Policy Advisory Group review. No changes to criteria. 3/02 Coding Format Change.


7/03 Format change. Removed ® and replaced with bullets in the covered and not covered section of the policy.

4/04 Benefits Application and Billing/Coding sections updated for consistency.
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6/4/07  Definition of Topical Hyperbaric Oxygen therapy added to Description section. Note: topical hyperbaric oxygen therapy is not considered hyperbaric oxygen pressurization. (See separate policy titled "Topical Hyperbaric Oxygen Therapy" MED1431). Indications for use of hyperbaric oxygen pressurization have been revised in the Covered and Noncovered sections. Wagner classification of wounds added to Covered section. The following statements were added to the Policy Guidelines section: While evidence for the treatment of acute carbon monoxide poisoning with HBO pressurization has failed to demonstrate improved health outcomes, this technology is accepted in medical practice as a standard medical therapy for the treatment of carbon monoxide poisoning. Code A4575 deleted. References updated. Specialty Matched Consultant Advisory Panel review 3/15/07, policy changes accepted as written. Notification given 6/4/07. Effective date 8/13/07. (adn)

5/5/08  Indications in the When Covered and When Not Covered sections converted from bulleted list to numbered list. The following indications added to the When Covered section: Item 6) soft- tissue radiation necrosis (radiation enteritis, cystitis, proctitis) and osteoradionecrosis and Item 7) pre-treatment and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw. The following indications are deleted from the Not Covered section: cystitis enteritis or proctitis and radiation necrosis (osteoradionecrosis and soft-tissue radiation necrosis). (adn)


9/14/10  Added the following to the list of non-covered indications in the When HBO is Not Covered section: “early treatment (beginning at completion of radiation therapy) to reduce side effects of radiation therapy and autism spectrum disorders.” Notification given 9/14/2010 for effective date of 12/21/2010. (adn)

4/26/11  Acute carbon monoxide poisoning and chronic refractory osteomyelitis added to the When HBO Is Covered section. Policy Guidelines sections updated with rationale. (adn)

10/30/12  Description section revised. The following statement was added to the Policy section: “Topical Hyperbaric Oxygen Therapy is considered investigational. BCBSNC does not cover investigational services.” Acute osteomyelitis, acute surgical and traumatic wounds, idiopathic femoral neck necrosis, chronic wounds, other than those in patients with diabetes who meet the criteria specified in the medically necessary statement, acute ischemic stroke, Bell’s palsy, and chronic arm lymphedema following radiotherapy for cancer added to the list of non-covered indications in the When HBO is Not Covered section. Utilization of hyperbaric oxygen information added to Policy Guidelines Section. Summary statements for Hyperbaric Oxygen Therapy and Topical Hyperbaric Oxygen Therapy added to Policy Guidelines Section. Added HCPCS code A4575 and E0446 to Billing/Coding section. Senior Medical Director review 10/14/2012. Notification given 10/30/2012 for effective date of 1/29/2013. (btw)

1/29/13  Specialty Matched Consultant Advisory Panel. No change to policy. (btw)

10/1/13  Added the following indications as investigational to the When Not Covered section: “Bisphosphonate-related osteonecrosis of the jaw, motor dysfunction associated with stroke, herpes zoster and vascular dementia”. Senior Medical Director review 9/14/2013. Reference added. Notification given 10/1/2013. Policy effective 12/10/2013. (btw)
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2/11/14  Specialty Matched Consultant Advisory Panel review 1/28/2014. No change to policy. (btw)

12/30/14  Added HCPCS code G0277 to Billing/Coding section effective as of 1/1/15. No change to policy. (td)


For policy titled, “Hyperbaric Oxygen Therapy”


12/30/16  Specialty Matched Consultant Advisory Panel review 11/30/2016. No change to policy statement. (an)

12/15/17  Specialty Matched Consultant Advisory Panel review 11/29/2017. No change to policy statement. (an)

11/9/18  Updated Description Section. Updated Policy Guidelines section. Specialty Matched Consultant Advisory Panel review 10/24/2018. No change to policy statement. (an)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.