Clinical Policy: Hyperbaric Oxygen Therapy

Reference Number: CP.MP.27
Last Review Date: 01/19

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Hyperbaric oxygen therapy (HBOT) is a medical treatment with pure oxygen at 2-3 times greater than normal atmospheric pressure. The elevated pressure and oxygen concentration allows higher levels of oxygen in the systemic circulation, creating hyperoxygenation of tissues. It is useful for conditions related to decreased tissue oxygenation. This policy addresses medical necessity criteria for the use of hyperbaric oxygen therapy.

Treatment may be carried out in either a monoplace pressurized chamber or in a larger multiplace pressurized chamber. The monoplace chamber is most common and accommodates one patient lying supine during therapy. The multiplace chamber accommodates several patients and medical personnel. Topical or limb specific therapy is a technique where therapy is applied to a specific wound or limb that requires treatment. The entire body is not exposed during this treatment.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that hyperbaric oxygen therapy is **medically necessary** for the following indications:

A. As a primary therapy for any of the following medical conditions:

1. Decompression illness, or air or gas embolism for up to 10 treatments depending on severity and length of time between occurrence and first treatment;
2. Acute carbon monoxide poisoning for up to 3 treatments in 24 hours when any of the following criteria are present:
   a. Unconscious at scene or hospital;
   b. CO level > 25%;
   c. In pregnant women, CO level > 20% or evidence of fetal distress;
   d. End-organ ischemia (eg, ECG changes, chest pain, altered mental status);
   e. Severe metabolic acidosis (pH < 7.1);
3. Severe anemia from class IV hemorrhage when unable to transfuse for medical or religious reasons when any of the following symptoms are present:
   a. Shock, systolic blood pressure < 90 mmHg, or pressure maintained by vasopressors;
   b. Changes in mental status from disorientation to coma;
   c. Ischemic changes of the myocardium as demonstrated by EKG;
   d. Ischemic gut;

   Treatments are considered medically necessary until red blood cells have been adequately replaced to alleviate the above signs and symptoms (Hgb of 6-8 g/dl).

B. As adjunctive treatment to accepted standard medical or surgical treatment for the following medical conditions:

1. Clostridial myostitis and myonecrosis (gas gangrene) for *up to 10 treatments when member is on dual IV antibiotic therapy and receiving surgical debridement*;
2. Crush injuries, suturing of severed limbs, and other acute traumatic ischemia when loss of function, limb, or life is threatened, including compartment syndrome. *Up to 20 treatments are considered medically necessary*;
3. Enhancement of healing of problematic wounds, such as one of the following:
   a. Initial treatment course of 20 sessions:
      i. Hypoxic wounds such as arterial insufficiency ulcers or diabetic ischemic ulcers: Members with non-reconstructable anatomy or whose ulcer is not healing despite revascularization, and both of the following:
         a) Wound is hypoxic (due to ischemia);
         b) The hypoxia is reversible by hyperbaric oxygenation;
      ii. Diabetic wounds of the lower extremities meeting all of the following criteria:
         a) Wagner grade III or greater;
         b) Failure of at least 30 days of standard wound care;
         c) Assessment of vascular status and correction of any vascular problems in the affected limb, if possible;
   b. Continued treatment with an additional 10 sessions, up to a maximum of 40 total sessions:
      i. Documented improvement includes wound measurements from prior to the most recent HBOT approval, and current wound measurements;
4. Intracranial abscess and any of the following:
   a. Failure to respond to standard surgical and antibiotic treatment;
   b. Multiple abscesses;
   c. Abscess in a deep or dominant location;
   d. Compromised health which would prevent normal healing;
   e. Surgery is contraindicated;
   Up to 20 treatments is considered medically necessary;
5. Necrotizing soft tissue infections when receiving surgical debridement and on appropriate IV antibiotic therapy.
   Approve initial treatment course of 30 sessions. If wound shows measureable signs of improvement after initial 30 treatments, additional follow-up treatment is considered medically necessary in increments of 10 sessions each. Further treatment after failure to show measureable improvement after each authorization period is considered not medically necessary;
6. Refractory osteomyelitis, a, b, & c, OR d
   a. Unresponsive to 4 weeks of culture-directed IV antibiotics, and
   b. Has undergone drainage and complete debridement of necrotic bone, and
   c. Antibiotics will continue during HBOT; OR
   d. In rare cases where surgical debridement may be debilitating or adversely affect the central nervous system, a trial of HBOT and antibiotic therapy may be approved prior to surgery;
   Approve initial treatment course of 30 sessions. If wound shows measureable signs of improvement after initial treatments, an additional 10 sessions are considered medically necessary. Further treatment after failure to show measureable improvement after each authorization period is considered not medically necessary;

7. Delayed soft tissue radiation injuries
   Approve initial treatment course of 30 sessions. If wound shows measureable signs of improvement after initial treatment, approve additional treatments in increments of 10, up to a total of 60 treatments. Further treatment after failure to show measurable improvement after each authorization period is considered not medically necessary;
8. Osteoradionecrosis of the jaw *prior to surgical debridement for 30 sessions and postoperatively for 10 sessions*;
9. Prevention of osteoradionecrosis in asymptomatic patients when surgery is required in a field which was previously irradiated with at least 6,800 cGy. *Twenty preoperative and 10 postoperative sessions are considered medically necessary*;
10. Compromised skin grafts and flaps, most common in members with compromised circulation, diabetes or vasculopathy, or irradiated tissue. Also appropriate for wound bed preparation prior to a flap in situation where surgical prognosis is poor (i.e. previous failed flap, radiation, etc.). Documentation should support that potential mechanical/surgical causes of flap compromise have been addressed or none are present
    Approve initial treatment course of 20 sessions. If wound shows measureable signs of improvement after initial treatments, an additional 10 sessions are considered medically necessary. Further treatment after failure to show measureable improvement after each authorization period is considered not medically necessary;
11. Idiopathic sudden sensorineural hearing loss refractory to systemic corticosteroids and HBOT is begun within two weeks of the onset of hearing loss *for up to 20 sessions;*
12. Central retinal artery occlusion *for an initial treatment course of 3 sessions. Further treatment will require additional review.*

C. Contraindications

1. Untreated pneumothorax;
2. Any current or prior treatment with bleomycin should consider risks and benefits;
3. Treatment with doxorubicin (Adriamycin®) within 2-3 days of HBOT
4. Patients undergoing current disulfuram (Antabuse) therapy should generally not receive multiple HBOT treatments. Emergent need for HBOT should consider risks and benefits;
5. Current cisplatin treatment, unless emergent HBOT is needed.

Relative contraindications include obstructive lung disease, upper respiratory or sinus infections, recent ear surgery or injury, fever, and claustrophobia.

II. Topical and/or limb specific hyperbaric oxygen therapy is considered **not medically necessary** because it is considered experimental/investigational.

Background

HBOT serves four primary functions. It increases the concentration of dissolved oxygen in the blood, enhancing perfusion. New blood vessels may develop from the formation of a collagen

matrix. Oxygen replaces inert gas in the bloodstream, which is then metabolized by the body; and it works as a bactericide.

Decompression illness and gas embolism
Decompression illness occurs when excess nitrogen forms bubbles in the tissues due to a reduction in ambient pressure, such as occurs with ascent from scuba diving. These bubbles are what cause the symptoms that are referred to as decompression illness or "the bends". Trapping of gas within the lungs during ascent can cause bubbles to be forced into the bloodstream (arterial gas embolism) where they can block the flow of blood or damage the lining of blood vessels supplying critical organs such as the brain. This can also occur in non-divers due to air entering the body during medical diagnostic or therapeutic procedures. Symptoms can include joint pain, numbness, tingling, skin rash, extreme fatigue, weakness of arms or legs, dizziness, loss of hearing, and in severe cases, complete paralysis or unconsciousness.

HBOT reduces the size of the air bubbles, drives the remaining gas into physical solution, and washes out inert gas from the bubble. The bubble either dissolves or shrinks enough to allow blood flow to return. The resumption of blood flow allows local swelling to subside with resultant improvement in circulation and oxygen supply. Concomitantly, the high levels of oxygen in the hyperbaric chamber have the potential to immediately restore cellular oxygen levels.

HBOT is the definitive treatment for decompression illness and gas embolism. The success of the treatment depends on the severity of the case and the delay of administration. If treatment is started within a few hours after onset of symptoms, most cases will successfully respond to a single treatment. In a small number of cases, repetitive treatments are recommended until no further improvement can be observed (<20 treatments).

Carbon monoxide poisoning
Carbon monoxide (CO) poisoning occurs by either accidental or intentional inhalation. Approximately 5-6% of patients evaluated in the emergency departments for CO poisoning are treated with HBOT. CO binds to hemoglobin in red blood cells at the sites usually utilized to carry oxygen. Oxygen, especially hyperbaric oxygen, accelerates the clearance of CO from the body, restoring oxygen delivery to tissues of the body. Hyperbaric oxygen has been shown to block a number of other mechanisms of toxicity from CO.

The benefit of HBOT for patients treated more than 12 hours after CO exposure is unproven. Rapidly providing treatment will result in the best outcomes for the individual. All patients meeting the criteria should receive at least one treatment as soon after exposure as possible, with possible additional therapy to limit or prevent further complications.

Clostridial myostitis and myonecrosis (gas gangrene)
Gas gangrene is an acute, rapidly progressing infection of soft tissues caused by one of several bacteria known as clostridium. The organisms causing gas gangrene produce poisons, known as exotoxins, which are capable of liquefying adjacent tissue and inhibiting local defense mechanisms. The infection can destroy healthy tissue and spread over the course of hours.

Exposure to high amounts of oxygen inhibits replication, migration, and exotoxins production of clostridium. Clostridium bacteria are anaerobic, meaning only a low level of oxygen is needed for it to grow. Repeated HBOT has the potential to slow progress of the infection while allowing antibiotics and surgical resection of infected tissue to control it. HBOT can decrease the intensity of surgery needed and can possibly prevent limb amputation that might otherwise be necessary.

HBOT should be implemented early in the treatment of these infections and can involve 2 to 3 daily sessions.

Crush injuries and other acute traumatic ischemias
Crush injuries and other acute ischemias, most often compartment syndromes, can occur from severe trauma such as motor vehicle accidents, falls, and gunshot wounds. With severe injuries, complication rates can be as high as 50%. Infection, non-healing fractures, and amputations are complications that can be decreased with the use of HBOT.

Treatments should be started as soon as possible after an injury and continued for 7 – 10 days. The oxygen delivered to the injured tissue reduces swelling and provides an environment more conducive to healing and fighting infections.

Enhancement of healing of problematic wounds
Problematic wounds are those that fail to respond to established medical and surgical treatments. Generally, HBOT is reserved for hypoxic wounds where hypoxia can be measured and reversed with a trial of supplemental oxygen or while in a hyperbaric chamber. Most of these are associated with diabetes or non-diabetic vascular insufficiency that occurs due to multiple local and systemic factors contributing to inhibition of tissue repair. The HBOT increases the oxygen level in the blood and tissues, inducing significant changes in the wound repair process that promotes healing. Treatment of diabetic foot wounds has shown a potential to decrease the incidence of limb amputations. Treatment protocols may include treatment twice daily initially, then once daily after symptoms have reversed.

Severe anemia when unable to transfuse for medical or religious reasons
For the case of HBOT for severe anemia, there must be a loss of enough red blood cell mass to compromise sufficient oxygen delivery to tissue in patients who cannot be transfused. Reasons for inability to transfuse include the threat of blood product incompatibility, concern for transmissible disease, or prohibition of transfusion due to religious beliefs. Intermittent use of HBOT is essential due to the toxicity of prolonged oxygen administration.

Intracranial abscess
Brain abscess formation can be a severe complication of sinus or bone infections of the skull. There are frequently multiple abscesses which can be very difficult to treat. Surgical drainage may cause unavoidable damage to surrounding tissues. Fine needle aspiration is becoming more common and generally avoids the problem of extensive damage. White blood cells may not have enough oxygen to effectively eliminate the infection deep in the abscess, away from their normal blood supply. Antibiotics also may not penetrate well into the brain abscess.

Most of these abscesses are caused by anaerobic bacteria. In the same manner as the treatment of gas gangrene, HBOT increases the oxygen level, exposing bacteria to levels that may inhibit or kill them. It also provides oxygen to white blood cells that improves their killing power. HBOT should be implemented early in the treatment regime, with 2 to 3 daily 90 minute sessions.

Necrotizing soft tissue infections
Clinical syndromes included in necrotizing soft tissue infections include crepitant anaerobic cellulitis, progressive bacterial gangrene, necrotizing fasciitis, and nonclostridial myonecrosis. These may result from either a single strain or a mixed population of bacteria, typically occurring after trauma, surgery, and/or around foreign bodies. Generally these infections occur in compromised hosts and induce conditions that further compromise normal host defense mechanisms by decreasing tissue oxygen levels and impairing white blood cells.

When surgical and antibiotic treatment fails, HBOT should be considered as adjunct treatment in specific cases where risk of morbidity and mortality are high. Treatment should be individualized but may start with 2 sessions per day until extension of necrosis has been halted, then once daily.

Refractory osteomyelitis
HBOT can be used as adjunct therapy for the treatment of refractory osteomyelitis. Osteomyelitis cause by anaerobic bacteria can be successfully treated by directly killing or inhibiting the growth of these organisms. Osteomyelitis can be associated with reduced segmental blood flow and consequent reduced oxygen tension that may limit neutrophil and macrophage activity. HBOT may increase the oxygen tension in infected bone and lead to successful healing.

HBOT should be reserved for treatment of advanced stages or types of osteomyelitis (III or IV) which have been unresponsive to 4 weeks of culture-directed antibiotic therapy and surgical debridement. Daily treatments are likely for four to six weeks.

Delayed radiation injury (soft tissue and bony necrosis)
Chronic complications from radiation therapy result from scarring and narrowing of the blood vessels within the area which received treatment. This process can progress to the point of tissue or bone necrosis. The high dose oxygen from HBOT is carried in the blood to the site of injury to be available for repair of the damage done by the narrowed blood vessels. Treatments are generally daily for 1-2 hours, up to 60 days.

HOBT is also appropriate for prophylaxis for osteoradionecrosis in patients who are asymptomatic but require surgery in a field which was previously irradiated with at least 6,800 cGy. This generally occurs with dental abstraction following head and neck radiation.

Compromised skin grafts and flaps
Common causes for failure of skin grafts include previous radiation to the wound area, diabetes, and certain infections due to inadequate oxygenation of the wound bed. In these cases, HBOT can increase the oxygen to the wound bed both before and after skin grafting. Lack of oxygen supplied to a graft due to factors such as age, nutritional status, smoking, and previous radiation

can result in inadequate blood flow to a new graft. HBOT can help minimize the amount of tissue which does not survive and also reduces the chance for repeat flap procedures.

Treatment regimens of 90 to 120 minutes daily for 6 to 30 days have been advocated. Initiation of therapy within 24 hours of grafting appears the most beneficial in these high risk cases.

Idiopathic sudden sensorineural hearing loss
The etiology of idiopathic sudden sensorienural hearing loss (ISSHL) is poorly understood. The cochlea and the structures within it require a high oxygen supply, although there is minimal direct vascular supply. The perilymph is the primary oxygen supply to the intracochlear structures. Perilymph oxygen tension is decreased significantly in patients with ISSHL, but HBOT can restore the arterial-perilymphatic oxygen levels enough to oxygenate the intracochlear structures and improve hearing.

Glucocorticoids are considered first-line treatment for ISSHL, with HBOT serving as adjunctive therapy. Best results have been found from initiating treatment within 14 days of the onset of hearing loss.

Central retinal artery occlusion
Central retinal artery occlusion (CRAO) is a rare emergent condition resulting in sudden, painless vision loss. Vision loss is usually dramatic and permanent, and the prognosis is poor, due to the lack of successful treatment options. HBOT is an exception, as it has been shown to hyperoxygenate the choroid, which in turn can supply 100% of the oxygen needed by the retina. Therapy must be initiated before the retina is irreparably damaged. Even with prompt treatment, some patients with occlusion of the ophthalmic artery may not respond to HBOT because alternate choroidal blood supply is blocked and cannot supply oxygen to the inner layers of the retina.

The American Heart Association rates the evidence for HBOT in CRAO as IIb, indicating that there is fair to good evidence to support its use. Due to the rarity of the condition, there are no randomized controlled trials to support its use.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2018, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
99183	Physician attendance and supervision of hyperbaric oxygen therapy, per session

HCPCS Codes	Description
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
A48.0	Gas gangrene
D50.0	Iron deficiency anemia secondary to blood loss (chronic
D62	Acute posthemorrhagic anemia
E10.51-E10.59	Type 1 diabetes mellitus with circulatory complications
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.51-E11.59	Type 2 diabetes mellitus with circulatory complications
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
G06.0	Intracranial abscess and granuloma
H34.10-H34.13	Central retinal artery occlusion
H91.20-H91.23	Sudden idiopathic hearing loss
I70.231-I70.239	Atherosclerosis of native arteries of right leg with ulceration
I70.241-I70.249	Atherosclerosis of native arteries of left leg with ulceration
I70.25	Atherosclerosis of native arteries of other extremities with ulceration
I70.331-I70.339	Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration
I70.341-I70.349	Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration
I70.35	Atherosclerosis of unspecified type of bypass graft(s) of other extremity with ulceration
I70.431-I70.439	Atherosclerosis of autologous vein bypass graft(s) of the right leg with ulceration
I70.441-I70.449	Atherosclerosis of autologous vein bypass graft(s) of the left leg with ulceration
I70.45	Atherosclerosis of autologous vein bypass graft(s) of other extremity with ulceration
I70.531-I70.539	Atherosclerosis of nonautologous biological bypass graft(s) of the right leg with ulceration
I70.541-I70.549	Atherosclerosis of nonautologous biological bypass graft(s) of the left leg with ulceration
I70.55	Atherosclerosis of nonautologous biological bypass graft(s) of other extremity with ulceration
I70.631-I70.639	Atherosclerosis of nonbiological bypass graft(s) of the right leg with ulceration
I70.641-I64.9	Atherosclerosis of nonbiological bypass graft(s) of the left leg with ulceration

ICD-10-CM Code	Description
I70.65	Atherosclerosis of nonbiological bypass graft(s) of other extremity with ulceration
I70.731-I70.739	Atherosclerosis of other type of bypass graft(s) of the right leg with ulceration
I70.741-I70.749	Atherosclerosis of other type of bypass graft(s) of the left leg with ulceration
I70.75	Atherosclerosis of other type of bypass graft(s) of other extremity with ulceration
I74.2	Embolism and thrombosis of arteries of the upper extremities
I72.3	Embolism and thrombosis of arteries of the lower extremities
I72.5	Embolism and thrombosis of iliac artery
L59.8	Other specified disorders of the skin and subcutaneous tissue related to radiation
L97.10-L97.929	Non-pressure chronic ulcer of lower limb, not elsewhere classified
M27.2	Inflammatory conditions of jaws
M27.8	Other specified diseases of jaws
M72.6	Necrotizing fasciitis
M86.30-M86.39	Chronic multifocal osteomyelitis
M86.40-M86.49	Chronic osteomyelitis with draining sinus
M86.50-M86.59	Other chronic hematogenous osteomyelitis
M86.60-M86.9	Other chronic osteomyelitis
M86.8X0-M86.8X9	Other osteomyelitis
O88.011-O88.03	Obstetric air embolism
S07.0XX+-S07.9XX+	Crushing injury of head
S17.0XX+-S07.9XX+	Crushing injury of neck
S28.0XX+-S28.229+	Crushing injury of thorax, and traumatic amputation of part of thorax
S35.511+-S35.513+	Injury of iliac artery
S38.001+-S38.03X+	Crushing injury and traumatic amputation of abdomen, lower back, pelvis and external genitalia
S45.001+-S45.009+	Injury of axillary artery
S47.1XX+-S47.9XX+	Crushing injury of shoulder and upper arm
S48.011+-S48.929+	Traumatic amputation of shoulder and upper arm
S57.00X+-S57.82X+	Crushing injury of elbow and forearm
S67.00X+-S67.92X+	Crushing injury of wrist, hand and fingers
S68.011+-S68.729+	Traumatic amputation of wrist, hands and fingers
S75.001+-S75.099+	Injury of femoral artery
S77.00X+-S77.22X+	Crushing injury of hip and thigh
S85.001+-S85.009+	Unspecified injury of popliteal artery
S85.801+-S85.899	Injury of other blood vessels at lower leg level
S87.00X+-S87.82X+	Crushing injury of lower leg
S97.00X+-S97.82X+	Crushing injury of ankle and foot

ICD-10-CM Code	Description
T57.3X1+-757.3X4+	Toxic effect of hydrogen cyanide
T58.01X+-T58.94X+	Toxic effect of carbon monoxide
T66.XXX+	Radiation sickness, unspecified
T70.0XX+-T70.9XX+	Effects of air pressure and water pressure
T79.0	Air embolism (traumatic)
T79.A11+-T79.9XX+	Traumatic compartment syndrome
T80.0XX+	Air embolism following infusion, transfusion and therapeutic injection
T81.4XX+	Infection following a procedure
T85.693+	Other mechanical complication of artificial skin graft and decellularized allodermis
T85.81-T85.89	Other specified complications of internal prosthetic devices, implants and grafts, not elsewhere classified
T86.820-T86.829	Complications of skin graft (allograft) (autograft)

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Developed		06/09
Clarified timeframe language for medically necessary treatment sessions	01/15	01/15
Updated template References reviewed and updated	02/16	03/16
Corrected HCPCS code as C code retired and G is correct	09/16	09/16
Updated criteria under IB 3b to more clearly state guidance for treatment and clarified when additional treatments would be considered medically necessary. Removed IB 3c from policy. Revised IB 6d to limit follow up treatments to an additional 10 sessions as guidelines state 20-40 postoperative HBOT sessions generally achieve sustained therapeutic benefit Revised IB 7a to state 30 sessions approved initially, up to a total of 60 sessions, in increments of 10 sessions. Revised IB 8 adding requirement for documentation supporting potential mechanical/surgical causes of flap compromise have been addressed or none are present. Revised number of sessions considered medically necessary. Added sudden sensory neural hearing loss as not medically necessary References reviewed and updated. ICD-10 codes added. Reviewed by specialist.	03/17	03/17
I.B.3.b. changed from diabetic foot ulcers to diabetic ulcers of the lower extremity. Expanded antimycotic brain abscess to intracranial abscess, and added criteria per Undersea and Hyperbaric Medicine Society (UHMS). Added idiopathic sudden sensorineural hearing loss and central retinal artery occlusion as indications, per UHMS. Updated coding to reflect criteria changes.	02/18	02/18

Reviews, Revisions, and Approvals	Date	Approval Date
For problematic wounds: removed requirement of transcutaneous oximetry; changed initial approval from 30 sessions to 20 sessions, and added option for an additional 10 up to 40 total. Specified that documentation must include measurements before and after HBOT.	10/18	10/18
Added that contraindication to bleomycin should consider risks and benefits. Removed contraindication regarding mafenide acetate (Sulfamylon®) as this would be relevant at the time of treatment and not part of the prior-authorization contraindications.	12/18	
References reviewed and updated. Specialist reviewed	01/19	01/19

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective

date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.