Medical services after brain death

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Policy contains: Determination of brain death; organ transplantation.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Medical care and services for a member who is determined to be brain-dead, including maintenance on a ventilator or artificial organ support before organs can be acquired, are investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Brain death is the permanent loss of the brain's ability to regulate bodily functions. When a patient is brain-dead, it is no longer possible for blood to flow to the brain. The heart is still beating only because of machines and medications that are being used. Although the person is dead, the machines make it appear as though they are alive. Because of this, it is important to understand that ventilators (breathing machines) are not considered "life support" in a brain-dead patient, since the patient's death has already been pronounced. The body cannot recover from brain death. Brain death did not exist before the invention and use of ventilators.

Brain death is different from coma and from vegetative state.

- Coma means a severely depressed level of consciousness, with complete unresponsiveness, however, brain function still exists. In contrast, in brain death, the patient has completely and irreversibly lost all brain function, and the patient is dead.
- Vegetative state means a state in which a patient is alive but has a brain injury that prevents awareness. When a patient is in vegetative state, the brainstem may continue to function, allowing continued capacity to breathe, and they may have wakefulness. However, they lack any awareness or meaningful interaction with their environment or those around them.

Brain death is caused by a catastrophic injury to the brain. Some of the more common causes are blocked blood vessels to the brain, burst blood vessels in the brain, a traumatic injury to the brain, cardiac arrest, brain infections, sudden liver failure, and other causes of severe brain swelling.

How brain death is determined

Physicians determine that brain death has occurred using methods to rule out any problems that can occasionally make a living patient appear dead (Wijdicks, 2010). Guidelines for adults (American Academy of Neurology, 2010a, 2010c) and for infants and children (Nakagawa, 2011) recommend the procedures and the tests to be used to check for coma, any reflexes, and the ability to breathe (see Appendices A and B).

In cases in which the member or their family have indicated a willingness to donate the patient's organs after death, to avoid conflicts of interest, the clinician on the care team who is authorized to declare death must not be a member of the Organ Procurement Organization or the organ recovery team (Organ Procurement and Transplant Network, 2020).

Findings

Brain death is a medical and legal determination of death (Scripko, 2011). It is an irreversible condition. No patients who were declared brain-dead have ever recovered (Neurocritical Care Society, 2020; Wijdicks, 2010). The body may be capable of being supported by artificial means for a limited period of time, either to have family gather or for possible organ donation, but this is not medically necessary for the patient who is no longer living. Ventilator and other machines are not maintained on the deceased.

The Uniform Determination of Death Act of 1980 is a technical act defining the criteria for neurologic and respiratory death (Uniform Law Commission, 2020). It has not been adopted in every state; therefore, brain death laws differ by state (American Academy of Neurology, 2010c; Association of Organ Procurement Organizations, 2020; Wang, 2017). Practices for determining brain death also vary across institutions (Greer, 2016). Most state laws in the United States do not require a brain scan testing for blood flow, or an electroencephalograph (a brain wave test, known as an "EEG"), however, they may be useful as part of the brain death determination in some circumstances (Stecker, 2016). A computed tomography scan or some form of neuroimaging is necessary to evaluate for the presence of a neurological catastrophe.

Once it is determined that the patient is brain-dead, no further medical services are necessary to sustain the patient. While a member may have advance directives or a living will stating that their life should be prolonged, this is not consistent with continued use of a ventilator after a determination of brain death, because recovery is not possible.

References

On March 5, 2020, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were: “brain death,” and “brain dead.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

5/2020: initial review date and clinical policy effective date: 6/2020

Appendix A

Update: Determining Brain Death in Adults (American Academy of Neurology, 2010c)

This content is slightly abridged. For the complete text, please refer to the full guideline. American Academy of Neurology. Update: determining brain death in adults. Clinician guideline summary: practical guidelines. June, 2010c. https://www.aan.com/Guidelines/home/GetGuidelineContent/432.

Practical (non-evidence-based) guidance for determination of brain death [in adults]

Many of the details of the clinical neurologic examination to determine brain death cannot be established by evidence-based methods. The detailed brain death evaluation protocol that follows is intended as a useful tool for clinicians. It must be emphasized that this guidance is opinion-based. Alternative protocols may be equally informative. The determination of brain death can be considered to consist of four steps.

I. The clinical evaluation (prerequisites)

A. Establish irreversible and proximate cause of coma

The cause of coma can usually be established by history, examination, neuroimaging, and laboratory tests. Exclude the presence of a CNS-depressant drug effect by history, drug screen, calculation of clearance using five times the drug's half-life (assuming normal hepatic and renal function), or, if available, drug plasma levels below the therapeutic range. Prior use of hypothermia (e.g., after cardiopulmonary resuscitation) for cardiac arrest may delay drug metabolism. The legal alcohol limit for driving (blood alcohol content 0.08%) is a practical threshold below which an examination to determine brain death could reasonably proceed. There should be no recent administration or continued presence of neuromuscular blocking agents (this can be defined by the presence of a train of four twitches with maximal ulnar nerve stimulation). There should be no severe electrolyte, acid-base, or endocrine disturbance (defined by severe acidosis or laboratory values markedly deviated from the norm).

B. Achieve normal core temperature

In most patients, a warming blanket is needed to raise the body temperature and maintain a normal or near-normal temperature (> 36°C). After the initial equilibration of arterial carbon dioxide (CO_2) with mixed central venous CO_2, the partial pressure of CO_2 ($PaCO_2$) rises steeply, but then more slowly when the body metabolism raises $PaCO_2$. To avoid delaying an increase in $PaCO_2$, normal or near normal core temperature is preferred during the apnea test.

C. Achieve normal systolic blood pressure

Hypotension from loss of peripheral vascular tone or hypovolemia (diabetes insipidus) is common; vasopressors or vasopressin are often required. Neurologic examination is usually reliable with a systolic blood pressure ≥100 mm Hg.

D. Perform one neurologic examination (sufficient to pronounce brain death in most U.S. states)

If a certain period of time has passed since the onset of the brain insult to exclude the possibility of recovery (in practice, usually several hours), one neurologic examination should be sufficient to pronounce brain death. However, some U.S. state statutes require two examinations. Legally, all physicians are allowed to determine brain death in most U.S. states. Neurologists, neurosurgeons, and intensive care specialists may have specialized expertise. It seems reasonable to require that all physicians making a determination of brain death be intimately familiar with brain death criteria and have demonstrated competence in this complex examination. Brain death statutes in the United States differ by state and institution. Some U.S. state or hospital guidelines require the examiner to have certain expertise.

II. The clinical evaluation (neurologic assessment)

A. Coma

- Patients must lack all evidence of responsiveness.

  Eye opening or eye movement to noxious stimuli is absent. Noxious stimuli should not produce a motor response other than spinally mediated reflexes. The clinical differentiation of spinal responses from retained motor responses associated with brain activity requires expertise.

B. Absence of brainstem reflexes

- Absence of pupillary response to a bright light is documented in both eyes.

  Usually the pupils are fixed in a midsize or dilated position (4 – 9 mm). Constricted pupils suggest the possibility of drug intoxication. When uncertainty exists, a magnifying glass should be used.

- Absence of ocular movements using oculocephalic testing and oculovestibular reflex testing.

  Once the integrity of the cervical spine is ensured, the head is briskly rotated horizontally and vertically. There should be no movement of the eyes relative to head movement. The oculovestibular reflex is tested by irrigating each ear with ice water (caloric testing) after the patency of the external auditory canal is confirmed. The head is elevated to 30 degrees. Each external auditory canal is irrigated (one ear at a time) with approximately 50 ml of ice water. Movement of the eyes should be absent during 1 minute of observation. Both sides are tested, with an interval of several minutes.

- Absence of corneal reflex.

  Absent corneal reflex is demonstrated by touching the cornea with a piece of tissue paper, a cotton swab, or squirts of water. No eyelid movement should be seen.

- Absence of facial muscle movement to a noxious stimulus.

  Deep pressure on the condyles at the level of the temporomandibular joints and deep pressure at the supraorbital ridge should produce no grimacing or facial muscle movement.

- Absence of the pharyngeal and tracheal reflexes.

  The pharyngeal or gag reflex is tested after stimulation of the posterior pharynx with a tongue blade or suction device. The tracheal reflex is most reliably tested by examining the cough response to tracheal suctioning. The catheter should be inserted into the trachea and advanced to the level of the carina followed by one or two suctioning passes.

C. Apnea

- Absence of a breathing drive.

  Absence of a breathing drive is tested with a CO_2 challenge. Documentation of an increase in $PaCO_2$ above normal levels is typical practice. It requires preparation before the test. Prerequisites: (1), norm tension; (2), normothermia; (3), euvolemia; (4), eucapnia ($PaCO_2$ 35 – 45 mm Hg); (5), absence of hypoxia; and (6), no prior evidence of CO_2 retention (i.e., chronic obstructive pulmonary disease, severe obesity).

  Procedure:

- Adjust vasopressors to a systolic blood pressure ≥ 100 mm Hg.
- Preoxygenate for at least 10 minutes with 100% oxygen to a PaO_2 > 200 mm Hg.
- Reduce ventilation frequency to 10 breaths per minute to eucapnia.
- Reduce positive end-expiratory pressure (PEEP) to 5 cm H_2O (oxygen desaturation with decreasing PEEP may suggest difficulty with apnea testing).
- If pulse oximetry oxygen saturation remains > 95%, obtain a baseline blood gas (partial pressure of oxygen [PaO_2], $PaCO_2$, pH, bicarbonate, base excess).
- Disconnect the patient from the ventilator.
- Preserve oxygenation (e.g., place an insufflation catheter through the endotracheal tube and close to the level of the carina and deliver 100% O_2 at 6 L/min).
- Look closely for respiratory movements for 8 – 10 minutes. Respiration is defined as abdominal or chest excursions and may include a brief gasp.
- Abort if systolic blood pressure decreases to 30 seconds. Retry procedure with T-piece, continuous positive airway pressure (CPAP) 10 cm H_2O, and 100% O_2 12 L/min.
- If no respiratory drive is observed, repeat blood gas (PaO_2, $PaCO_2$, pH, bicarbonate, base excess) after approximately 8 minutes.
- If respiratory movements are absent and arterial PCO_2 is ≥ 60 mm Hg (or 20 mm Hg increase in arterial PCO_2 over a baseline normal arterial PCO_2), the apnea test result is positive (i.e., supports the clinical diagnosis of brain death).
- If the test is inconclusive but the patient is hemodynamically stable during the procedure, it may be repeated for a longer period of time (10 – 15 minutes) after the patient is again adequately preoxygenated.

III. Ancillary tests

In clinical practice, EEG, cerebral angiography, nuclear scan, and transcranial Doppler (TCD) are currently used ancillary tests in adults. Most hospitals will have the logistics in place to perform and interpret an EEG, nuclear scan, or cerebral angiogram, and these three tests may be considered the

preferred tests. Ancillary tests can be used when uncertainty exists about the reliability of parts of the neurologic examination or when the apnea test cannot be performed. In some protocols, ancillary tests are used to shorten the duration of the observation period.

The interpretation of each of these tests requires expertise. In adults, ancillary tests are not needed for the clinical diagnosis of brain death and cannot replace a neurologic examination. Physicians ordering ancillary tests should appreciate the disparities between tests and the potential for false positives (i.e., the test suggests brain death, but the patient does not meet clinical criteria). Rather than ordering ancillary tests, physicians may decide not to proceed with the declaration of brain death if clinical findings are unreliable.

IV. Documentation

The time of brain death is documented in the medical records. Time of death is the time the arterial PCO_2 reached the target value. In patients with an aborted apnea test, the time of death is when the ancillary test has been officially interpreted. A checklist is filled out, signed, and dated. Federal and state law requires the physician to contact an organ procurement organization following determination of brain death.

Appendix B

Summary recommendations for the diagnosis of brain death in neonates, infants, and children (Nakagawa, 2011)

Recommendation	Evidence score	Recommendation score
1. Determination of brain death in neonates, infants and children relies on a clinical diagnosis that is based on the absence of neurologic function with a known irreversible cause of coma. Coma and apnea must coexist to diagnose brain death. This diagnosis should be made by physicians who have evaluated the history and completed the neurologic examinations.	High	Strong
2. Prerequisites for initiating a brain death evaluation		
a. Hypotension, hypothermia, and metabolic disturbances that could affect the neurological examination must be corrected prior to examination for brain death.	High	Strong
b. Sedatives, analgesics, neuromuscular blockers, and anticonvulsant agents should be discontinued for a reasonable time period based on elimination half-life of the pharmacologic agent to ensure they do not affect the neurologic examination. Knowledge of the total amount of each agent (mg/kg) administered since hospital admission may provide useful information concerning the risk of continued medication effects. Blood or plasma levels to confirm high or supratherapeutic levels of anticonvulsants with sedative effects that are not present should be obtained (if available) and repeated as needed or until the levels are in the low to mid therapeutic range.	Moderate	Strong
c. The diagnosis of brain death based on neurologic examination alone should not be made if supratherapeutic or high therapeutic levels of sedative agents are present. When levels are in the low or in the mid-therapeutic range, medication effects sufficient to affect the results of the neurologic examination are unlikely. If uncertainty remains, an ancillary study should be performed.	Moderate	Strong

Recommendation	Evidence score	Recommendation score
d. Assessment of neurologic function may be unreliable immediately following cardiopulmonary resuscitation or other severe acute brain injuries and evaluation for brain death should be deferred for 24 to 48 hours or longer if there are concerns or inconsistencies in the examination.	Moderate	Strong
3. Number of examinations, examiners and observation periods		
a. Two examinations including apnea testing with each examination separated by an observation period are required.	Moderate	Strong
b. The examinations should be performed by different attending physicians involved in the care of the child. The apnea test may be performed by the same physician, preferably the attending physician who is managing ventilator care of the child.	Low	Strong
c. Recommended observation periods:		
(1) 24 hours for neonates (37 weeks gestation to term infants 30 days of age)	Moderate	Strong
(2) 12 hours for infants and children (> 30 days to 18 years).		
d. The first examination determines the child has met neurologic examination criteria for brain death. The second examination, performed by a different attending physician, confirms that the child has fulfilled criteria for brain death.	Moderate	Strong
e. Assessment of neurologic function may be unreliable immediately following cardiopulmonary resuscitation or other severe acute brain injuries and evaluation for brain death should be deferred for 24 to 48 hours or longer if there are concerns or inconsistencies in the examination.	Moderate	Strong
4. Apnea testing		
a. Apnea testing must be performed safely and requires documentation of an arterial $Paco_2$ 20 mm Hg above the baseline $Paco_2$ and ≥ 60 mm Hg with no respiratory effort during the testing period to support the diagnosis of brain death. Some infants and children with chronic respiratory disease or insufficiency may only be responsive to supranormal $Paco_2$ levels. In this instance, the $Paco_2$ level should increase to ≥ 20 mm Hg above the baseline $Paco_2$ level.	Moderate	Strong
b. If the apnea test cannot be performed due to a medical contraindication or cannot be completed because of hemodynamic instability, desaturation to <85%, or an inability to reach a $Paco_2$ of 60 mm Hg or greater, an ancillary study should be performed.	Moderate	Strong
5. Ancillary studies		
a. Ancillary studies (EEG and radionuclide CBF) are not required to establish brain death unless the clinical examination or apnea test cannot be completed	Moderate	Strong
b. Ancillary studies are not a substitute for the neurologic examination.	Moderate	Strong
c. For all age groups, ancillary studies can be used to assist the clinician in making the diagnosis of brain death to reduce the observation period or when (i) components of the examination or apnea testing cannot be completed safely due to the underlying medical condition of the patient; (ii) if there is uncertainty about the results of the neurologic examination; or (iii) if a medication effect may interfere with evaluation of the patient. If the ancillary study	Moderate	Strong

Recommendation	Evidence score	Recommendation score
supports the diagnosis, the second examination and apnea testing can then be performed. When an ancillary study is used to reduce the observation period, all aspects of the examination and apnea testing should be completed and documented.		
d. When an ancillary study is used because there are inherent examination limitations (i.e., i to iii), then components of the examination done initially should be completed and documented.	High	Strong
e. If the ancillary study is equivocal or if there is concern about the validity of the ancillary study, the patient cannot be pronounced dead. The patient should continue to be observed until brain death can be declared on clinical examination criteria and apnea testing, or a follow-up ancillary study can be performed to assist with the determination of brain death. A waiting period of 24 hours is recommended before further clinical reevaluation or repeat ancillary study is performed. Supportive patient care should continue during this time period.	Moderate	Strong
6. Declaration of death		
a. Death is declared after confirmation and completion of the second clinical examination and apnea test.	High	Strong
b. When ancillary studies are used, documentation of components from the second clinical examination that can be completed must remain consistent with brain death. All aspects of the clinical examination, including the apnea test, or ancillary studies must be appropriately documented.	High	Strong
c. The clinical examination should be carried out by experienced clinicians who are familiar with infants and children, and have specific training in neurocritical care.	High	Strong