Medical and Behavioral Health Policy Activity

Policies Effective: November 4, 2024 Notification Posted: September 3, 2024

Policies Developed

- **Remote Electrical Neuromodulation for Migraines, II-295**

  Remote electrical neuromodulation is considered **EXPERIMENTAL/INVESTIGATIVE** for the treatment or prevention of migraine due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies Revised

- **Implanted Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea, IV-80**

  Note: For other treatments of obstructive sleep apnea, please see medical policy IV-07, *Treatment of Obstructive Sleep Apnea and Snoring in Adults.*

I. Hypoglossal nerve stimulation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in adults with obstructive sleep apnea when **ALL** of the following criteria are met:

- Age ≥ 18 years; **AND**
- Body mass index (BMI) ≤ 35 kg/m^2; **AND**
- Apnea/hypopnea index (AHI), respiratory disturbance index (RDI), or respiratory event index (REI) ≥ 15 with ≤ 25% central apneas; **AND**
- Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), including documentation that the patient was intolerant of PAP for a minimum of 12 weeks, despite multiple models of facial masks and nasal pillows, and consultation with a sleep specialist; **AND**
- Absence of the following:
  - Complete concentric collapse at the soft palate level;
  - Severe or restricted obstructive pulmonary disease;
  - Neuromuscular disease affecting the respiratory tract;
  - Severe valvular heart disease;
  - Pregnancy or planned pregnancy;
  - Any other anatomical findings that would compromise performance of the device (e.g., tonsil size 3 or 4 per tonsillar hypertrophy grading scale).

II. Hypoglossal nerve stimulation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in adolescents or young adults with Down syndrome and obstructive sleep apnea syndrome (OSA) when **AL**L of the following criteria are met:

- Age 10 to 21 years; **AND**
- Body mass index ≤ 95th percentile for age; **AND**
- AHI >10 and <50 with ≤ 25% central apneas after prior adenotonsillectomy; **AND**
- Have either tracheotomy or ineffectively treated with CPAP due to noncompliance, discomfort, undesirable side effects, persistent symptoms despite compliance use, or refusal to use the device; **AND**
- Absence of complete concentric collapse at the soft palate level.

III. All other uses of hypoglossal nerve stimulation are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Sleep study confirming diagnosis of sleep apnea must show moderate to severe OSA, performed within the previous year;
2. A summary of all conservative OSA treatments attempted, including length of trial and results;
3. Results of drug-induced sleep endoscopy procedure.

- **Plasma Exchange, II-192**

I. Initial Review

Plasma exchange may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for the following indications, when performed by or in consultation with a specialist:

- **Autoimmune Diseases**
  - Catastrophic antiphospholipid syndrome (CAPS);
  - Cryoglobulinemia, severe mixed.
- **Hematologic Conditions**
  - Atypical hemolytic uremic syndrome (aHUS);
  - HELLP syndrome of pregnancy (characterized by hemolysis [H], elevated liver enzymes [EL], and low platelet [LP] counts);
  - Hyperviscosity syndromes associated with monoclonal gammopathies (e.g., multiple myeloma, Waldenström's macroglobulinemia);
  - Myeloma with acute renal failure (myeloma cast nephropathy);
  - Thrombotic microangiopathy associated with ticlopidine;
  - Thrombotic thrombocytopenic purpura (TTP).
- **Neurologic Conditions**
  - Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome);
  - Chronic inflammatory demyelinating polyradiculoneuropathy (CIDP);
  - Multiple sclerosis, with acute central nervous system inflammatory demyelination;
  - Myasthenia gravis in crisis or as part of preoperative preparation;
  - *N*-methyl-D-aspartate (NMDA) receptor antibody encephalitis;
  - Neuromyelitis optica spectrum disorders, acute disease (excluding maintenance therapy);
  - Paraproteinemia polyneuropathy; immunoglobulin A and G;
  - Pediatric acute-onset neuropsychiatric syndrome (PANS)/Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) exacerbation;
  - Progressive multifocal leukoencephalopathy (PML) associated with natalizumab.
- **Renal Diseases**
  - Antiglomerular basement membrane disease (Goodpasture syndrome);
  - Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (e.g., granulomatosis with polyangiitis [also known as Wegener's granulomatosis], microscopic polyangiitis) with associated renal failure;
  - Dense deposit disease with factor H deficiency and/or elevated C3 nephritic factor.
- **Transplantation**
  - ABO-incompatible hematopoietic stem cell transplantation;
  - ABO-incompatible solid organ transplantation:
    1. heart (infants);
    2. kidney;

- Focal segmental glomerulosclerosis after renal transplant;
- Renal transplantation: antibody-mediated rejection or human leukocyte antigen desensitization.;
- Liver transplantation (desensitization, living donor).

- **Genetic Disorders**
  - Wilson disease (fulminant).

II. Renewal Review

Plasma exchange may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- The patient has been previously approved for therapy through the initial review process; **AND**
- The renewal request is for the same indication previously approved; **AND**
- The patient has shown positive clinical response from previous plasma exchange treatment (e.g., reduced number and/or severity of infections, decreased use/elimination of prophylactic antibiotics, functional improvement).

III. Experimental/Investigative Uses

Plasma exchange is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to the following conditions, due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- ABO-incompatible solid organ transplant: liver;
- Acute disseminated encephalomyelitis;
- Alzheimer's disease;
- Amyotrophic lateral sclerosis;
- Antineutrophil cytoplasmic antibody (ANCA)-associated rapidly progressive glomerulonephritis (granulomatosis with polyangiitis, microscopic polyangiitis) without renal failure;
- Aplastic anemia;
- Asthma;
- Autoimmune hemolytic anemia; warm autoimmune hemolytic anemia; cold agglutinin disease;
- Chronic fatigue syndrome;
- Coagulation factor inhibitors;
- Dermatomyositis and polymyositis;
- Focal segmental glomerulosclerosis (other than after renal transplant);
- Heart transplant rejection treatment;
- Hemolytic uremic syndrome, typical (diarrheal-related);
- Idiopathic thrombocytopenic purpura (ITP), refractory or nonrefractory;
- Inclusion body myositis;
- Lambert-Eaton myasthenic syndrome;
- Multiple sclerosis with chronic progressive or relapsing remitting course;
- Overdose and poisoning (e.g., mushroom poisoning);
- Paraneoplastic syndromes;
- Paraproteinemia polyneuropathy IgM;
- Pemphigus vulgaris;
- Phytanic acid storage disease (Refsum disease);
- POEMS (polyneuropathy, organomegaly, endocrinopathy, M protein, skin changes);
- Psoriasis;
- Red blood cell alloimmunization in pregnancy;
- Rheumatoid arthritis;

- Sepsis;
- Scleroderma (systemic sclerosis);
- Stiff person syndrome;
- Sydenham chorea;
- Systemic lupus erythematosus (including systemic lupus erythematosus nephritis);
- Thyrotoxicosis.

- **Transcranial Magnetic Stimulation, X-14**

NOTE: Transcranial Magnetic Stimulation (TMS) criteria in sections I and II apply to the following modalities: conventional or repetitive rTMS, theta-burst TMS, and deep brain/deep TMS.

Transcranial Magnetic Stimulation

I. Transcranial magnetic stimulation may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a treatment of major depressive disorder when **ALL** of the following criteria have been met:

- Confirmed diagnosis of severe major depressive disorder (single or recurrent) which includes documentation from standardized rating scales that reliably measure depressive symptoms (e.g., Hamilton Rating Scale for Depression or Montgomery-Asberg Depression Rating Scale); **AND**
- 18 years of age or older; **AND**
- Any ONE of the following:
  - Inadequate response to 3 or more trials of antidepressants from at least 2 different therapeutic classes (e.g. selective serotonin reuptake inhibitors [SSRIs], serotonin-norepinephrine reuptake inhibitors [SNRIs], tricyclic antidepressants [TCAs]), including at least one failed trial of augmentation; **OR**
  - Documented intolerance of a therapeutic dose, FDA labeled contraindication, or hypersensitivity to four or more antidepressants from at least two different therapeutic classes; **OR**
  - History of response to ғTMS in a previous depressive episode (at least 3 months since the prior episode); **AND**
- Ongoing active psychotherapy; **AND**
- NONE of the following conditions are present:
  - Seizure disorder or any history of seizure with increased risk of future seizure; **OR**
  - Presence of psychotic symptoms in the current depressive episode; **OR**
  - Acute suicidal risk, catatonia or life-threatening inanition; **OR**
  - Neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system (CNS); **OR**
  - Presence of an implanted magnetic-sensitive medical device located 30 centimeters or less from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator (ICD), pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents; **AND**
- Prescribed and provided by, or under the direct supervision of, a psychiatrist or advanced practice psychiatric provider trained in the use of the specific device; **AND**
- Not used concomitantly with esketamine (Spravato™) or other ketamine products.

II. Transcranial magnetic stimulation (ғTMS) is considered **EXPERIMENTAL/INVESTIGATIVE** for all other uses including but not limited to the following due to a lack of evidence demonstrating an impact on health outcomes:

- Continued treatment with ғTMS as maintenance therapy
- Treatment of all other psychiatric/neurologic disorders, including but not limited to bipolar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches.

Navigated Transcranial Magnetic Stimulation

III. Navigated transcranial magnetic stimulation (nTMS) is considered **EXPERIMENTAL/ INVESTIGATIVE** for all indications due to a lack of evidence demonstrating an impact on health outcomes.

- **Ventricular Assist Devices and Total Artificial Hearts, IV-86**

I. Implantable Ventricular Assist Devices

- Implantable ventricular assist devices with FDA approval may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a bridge to recovery in patients with a potentially reversible condition, who meet ONE of the following criteria:
  - Acute cardiogenic shock when recovery is expected; OR
  - Following cardiac surgery when the patient cannot be weaned from cardiopulmonary bypass.
- Implantable ventricular assist devices with FDA approval may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a bridge to heart transplantation in adults who meet one of the following criteria:
  - The patient is currently listed as a heart transplantation candidate and is not expected to survive until a donor heart can be obtained; **OR**
  - The patient is undergoing evaluation to determine candidacy for heart transplantation.
- Implantable ventricular assist devices with FDA approval, including humanitarian device exemptions, may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a bridge to heart transplantation in children and adolescents who meet one of the following criteria:
  - The patient is currently listed as a heart transplantation candidate and is not expected to survive until a donor heart can be obtained; **OR**
  - The patient is undergoing evaluation to determine candidacy for heart transplantation.
- Implantable ventricular assist devices with FDA approval may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as destination therapy in patients with end-stage heart failure who are ineligible for heart transplantation and who meet one of the following criteria:
  - Symptoms of New York Heart Association (NYHA) class IV heart failure for ≥ 60 days; **OR**
  - Symptoms of NYHA class III/IV for at least 28 days and dependent on intra-aortic balloon pump for ≥ 14 days or IV inotropic agents, with two failed weaning attempts.
- Implantable ventricular assist devices are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

II. Percutaneous Ventricular Assist Devices

- Percutaneous ventricular assist devices (pVADs) with FDA approval may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when used for the following indications:
  - Short term (≤ 14 days) circulatory support for treatment of cardiogenic shock; or
  - Short term (≤ 14 days) circulatory support for patients who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.
- Percutaneous ventricular assist devices are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

III. Total Artificial Hearts

- Total artificial hearts, used in accordance with their FDA approval, may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as a bridge to heart transplantation for patients with biventricular failure who are currently listed as heart transplantation candidates.

- Total artificial hearts are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Policies Inactivated
None

Policies Delegated to eviCore
None