National Coverage Determinations

Your Source for updates to Medicare-covered services

The Centers for Medicare & Medicaid Services (CMS) sometimes change the coverage rules that apply to an item or service that may be or may have been covered by Medicare. When this happens, CMS issues a National Coverage Determinations (NCD). An NCD will tell us:

- What benefits and services are covered
- What benefits and services are changing
- What Medicare will pay for an item or service

You are able to access the most updated information related to NCDs by accessing the following website: https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx

CMS has issued the NCD notices:

Effective 1/21/2020: Acupuncture for Chronic Lower Back Pain (cLBP)

This is effective for dates of service on and after **January 21, 2020.**

Acupuncture is the selection and manipulation of specific acupuncture points by a variety of needling and non-needling techniques.

CMS will cover acupuncture for Medicare patients with chronic Lower Back Pain (cLBP).
cLBP is defined as:

- Lasting 12 weeks or longer
- nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease)
- not associated with surgery
- not associated with pregnancy

Up to 12 visits in 90 days are covered. An additional 8 sessions will be covered for those patients demonstrating an improvement. No more than 20 acupuncture treatments may be administered annually.

Treatment must be discontinued if the patient is not improving or is regressing.

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

This summarizes CMS transmittal R10128NCD.

Effective 7/02/2019: Ambulatory blood pressure monitoring (ABPM)

This is effective for dates of service on and after **July 2, 2019.**

The Centers for Medicare & Medicaid Services (CMS) has released a change request that informs contractors that effective for claims with dates of service on and after July 2, 2019, Medicare will allow for coverage of ABPM for beneficiaries under certain conditions.

ABPM is a diagnostic test that allows for the identification of various types of high blood pressure. ABPM devices are small portable machines that are connected to a blood pressure cuff worn by patients. The devices record blood pressure at regular periods over 24 to 48 hours while the patient goes about his or her normal activities, including sleep. The recording is interpreted by a physician or nonphysician practitioner, and appropriate action is taken based on the findings.

As of July, 2, 2019, CMS will cover ABPM for the diagnosis of hypertension in Medicare beneficiaries under the following circumstances:

1. For beneficiaries with suspected white coat hypertension (WCH), which is defined as average office systolic blood pressure (BP) greater than 130 mmHg but less than 160 mmHg or diastolic BP greater than 80 mmHg but less than 100 mmHg on 2 separate clinic/office visits with at least 2 separate measurements made at each visit and with at least 2 BP measurements taken outside the office that are less than 130/80 mmHg
2. For beneficiaries with suspected masked hypertension, which is defined as average office BP between 120 mmHg and 129 mmHg for systolic BP or between 75 mmHg and 79 mmHg for diastolic BP on 2 separate clinic/office visits with at least 2 separate measurements made at each visit and with at least 2 BP measurements taken outside the office that are greater than or equal to 130/80 mmHg

ABPM devices must be:

- Capable of producing standardized plots of BP measurements for 24 hours with daytime and nighttime windows and normal BP bands demarcated
- Provided to patients with oral and written instructions, with a test run taking place in the physician’s office
- Interpreted by the treating physician or treating nonphysician practitioner

Effective July 2, 2019, for eligible patients, ABPM is covered once per year.

Effective 2/15/2019: Vagus nerve stimulation (VNS)

This is effective for dates of service on and after **February 15, 2019.**

The Centers for Medicare & Medicaid Services (CMS) has issued Original Medicare instructions regarding coverage of VNS, national coverage determination (NCD) for treatment resistant depression (TRD).

An NCD that expands coverage is also binding on a Medicare Advantage organization.

Vagus Nerve Stimulation (VNS) is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead.

Effective for services performed on or after **February 15, 2019**, the Centers for Medicare & Medicaid Services (CMS) covers FDA-approved VNS devices for TRD through Coverage with Evidence Development (CED) when offered in a CMS-approved clinical study. For more information on the approval of CED for VNS, go to https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/VNS

The following criteria must be used to identify patients with TRD:

- The patient must be in a major depressive disorder (MDD) episode for ≥ two years or have had at least four episodes of MDD, including the current episode. In order to confirm the patient has MDD, accepted diagnostic criteria from the most current edition of the Diagnostic and Statistical Manual for Mental Disorder (DSM) and a structured clinical assessment are to be used.
- The patient's depressive illness meets a minimum criterion of four prior failed treatments of adequate dose and duration as measured by a tool designed for this purpose.
- The patient is experiencing a major depressive episode (MDE) as measured by a guideline recommended depression scale assessment tool on two visits, within a 45-day span prior to implantation of the VNS device.

Patients must maintain a stable medication regimen for at least four weeks before device implantation.

If patients with bipolar disorder are included, the condition must be carefully characterized. Patients must not have:

- Current or lifetime history of psychotic features in any major depressive episode
- Current or lifetime history of schizophrenia or schizoaffective disorder
- Current or lifetime history of any other psychotic disorder
- Current or lifetime history of rapid cycling bipolar disorder
- Current secondary diagnosis of delirium, dementia, amnesia, or other cognitive disorder
- Current suicidal intent
- Treatment with another investigational device or investigational drugs

VNS is non-covered for the treatment of TRD when furnished outside of a CMS-approved CED study and all other indications of VNS for the treatment of depression are non-covered.

Patients implanted with a VNS device for TRD may receive a VNS device replacement if it is required due to the end of battery life, or any other device-related malfunction.

This summarizes CMS Transmittal R10145NCD.

Effective 4/10/2018: Magnetic Resonance Imaging (MRI)

This is effective for service on or after **April 10, 2018.**

CMS determined that MRI for Medicare beneficiaries with the below devices is reasonable and necessary under certain circumstances.

- Implanted Pacemaker (PM)
- Implantable Cardioverter Defibrillator (ICD)
- Cardiac Resynchronization Therapy Pacemaker (CRT-P)
- Cardiac Resynchronization Therapy Defibrillator (CRT-D)

CMS will expand coverage:

- to include CRT-P or CRT-D devices
- for beneficiaries who have an implanted FDA-approved, ICD, CRT-P, or CRT-D

- for beneficiaries with an implanted PM, ICD, CRT-P, or CRT-D device without FDA labeling specific to use in an MRI environment if certain conditions are met

CMS will also remove the Coverage with Evidence Development (CED) requirement.

This summarizes CMS transmittal 208.

Effective 3/16/2018: Next Generation Sequencing (NGS)

This is effective for service on or after **March 16, 2018.**

The Centers for Medicare & Medicaid Services (CMS) reviewed the evidence for laboratory diagnostic tests using NGS in patients with cancer. They determined that some tests could improve health outcomes for Medicare beneficiaries with advanced cancer. Testing will be covered for beneficiaries with:

- recurrent, relapsed, refractory or metastatic cancer
- advanced stages III or IV cancer if the beneficiary either:
    - has not been previously tested using the same NGS test for the same primary diagnosis of cancer or
    - will get repeat testing using the same NGS test only when the treating physician gives a new primary cancer diagnosis and there will be further cancer treatment (e.g., therapeutic chemotherapy)

The test must be ordered by the treating physician, performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, and have all of the following requirements met:

- Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic; and,
- an FDA-approved or -cleared indication for use in that patient's cancer; and,
- results provided to the treating physician for management of the patient using a report template to specify treatment options

This summarizes CMS transmittal 215 (replacing 214 and 210).

Effective 2/15/2018: Implantable Cardiac Defibrillators (ICD)

This is effective for service on or after **February 15, 2018.**

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias.

CMS will cover ICDs for the following patient indications.

1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause.
2. Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause.

3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy.

Additional indications effective for services performed on or after October 1, 2003:

1. Coronary artery disease with a documented prior MI, a measured left ventricular ejection fraction (LVEF) ≤ 0.35, and inducible, sustained VT or VF at EP study. (The MI must have occurred more than 40 days prior to defibrillator insertion. The EP test must be performed more than 4 weeks after the qualifying MI.)
2. Documented prior MI and a measured LVEF ≤0.30 and a QRS duration of >120 milliseconds (the QRS restriction does not apply to services performed on or after January 27, 2005). Restrictions apply.
3. Patients with ischemic dilated cardiomyopathy (IDCM), documented prior MI, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
4. Patients with non-ischemic dilated cardiomyopathy (NIDCM) > 9 months, NYHA Class II and III heart failure, and measured LVEF ≤ 35%;
5. Patients who meet all current Centers for Medicare & Medicaid Services (CMS) coverage requirements for a cardiac resynchronization therapy (CRT) device and have NYHA Class IV heart failure.
6. Patients with NIDCM >3 months, NYHA Class II or III heart failure, and measured LVEF ≤ 35%, only if the following additional criteria are also met. See documentation for criteria.

This summarizes CMS transmittal 213 (replacing 209 & 211).

Effective 5/25/17: Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

The Centers for Medicare and Medicaid Services (CMS) covers supervised exercise therapy (SET) for beneficiaries with intermittent claudication (IC) for the treatment of symptomatic Peripheral Artery Disease (PAD). Up to 36 sessions over a 12-week period are covered when National Coverage Determination (NCD) criteria are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 1/18/17: Leadless Pacemakers

The Centers for Medicare & Medicaid Services (CMS) covers leadless pacemakers through Coverage with Evidence Development (CED) and when National Coverage Determination criteria are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 9/28/16: Screening for Hepatitis B Virus (HBV) Infection

The Centers for Medicare & Medicaid Services (CMS) covers screening for Hepatitis B Virus infection with the appropriate U. S. Food and Drug Administration (FDA) approved laboratory tests, when National Coverage Determination (NCD) eligibility criteria are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 2/8/16: Percutaneous Left Atrial Appendage

Closure (LAAC)

The Centers for Medicare & Medicaid Services (CMS) covers percutaneous LAAC for non-valvular atrial fibrillation through Coverage with Evidence Development when criteria per the National Coverage Determination are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 7/29/15: Speech Generating Device Medicare Administrative

Contractors acting within their respective jurisdictions have discretion to cover or not cover speech generating devices based on their individual reasonable and necessary determinations. In accordance with CMS guidance, Solis Health Plans (HMO) will follow the directions of any issued determinations.

Effective 7/9/15: Testing for Human Papillomavirus (HPV)

The Centers for Medicare & Medicaid Services (CMS) covers Human Papillomavirus (HPV) testing as an additional preventive service benefit under the Medicare program, in conjunction with the Pap smear test, if National Coverage Determination (NCD) eligibility criteria are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 2/5/15: Screening for Lung Cancer with Low Dose Computed Tomography (LDCT)

The Centers for Medicare & Medicaid Services (CMS) covers a lung cancer screening counseling and shared decision-making visit, and for appropriate beneficiaries, annual screening for lung cancer with low dose computed tomography (LDCT) under the Medicare program if National Coverage Determination (NCD) eligibility criteria NCD are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 10/9/14: Colorectal Cancer Screening Tests

The Centers for Medicare & Medicaid Services (CMS) has determined that The Cologuard™ test is covered once every three years for Medicare beneficiaries that meet specific criteria. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 8/7/14: Transcatheter Mitral Valve Repair (TMVR)

The Centers for Medicare & Medicaid Services (CMS) covers TMVR for mitral regurgitation when furnished under coverage with evidence development (CED) and additional criteria is met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 6/2/14: Screening for Hepatitis C Virus (HCV) in Adults

CMS will cover screening for HCV with the approved laboratory tests when ordered by the beneficiary's primary care physician (PCP) or practitioner within the context of a primary care setting and performed by an eligible Medicare provider for these services, for beneficiaries who meet specific conditions. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified conditions are met.

Effective 2/18/14: Cardiac Rehabilitation Programs for Chronic Heart Failure

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is enough to expand coverage for cardiac rehabilitation services to beneficiaries with stable, chronic heart failure who meet specific criteria. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 1/9/14: Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)

The Centers for Medicare & Medicaid Services (CMS) has determined that PILD will be covered when provided to beneficiaries with LSS who are enrolled in an approved clinical study that meets the criteria. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified conditions are met.

Effective 9/27/13: Beta Amyloid Positron Emission Tomography (PET) in Dementia and Neurodegenerative Disease

The Centers for Medicare & Medicaid Services (CMS) will only allow coverage with evidence development (CED) for Positron Emission Tomography (PET) beta amyloid imaging (also referred to as amyloid-beta (Aβ)) when specific conditions are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 8/13/13: Single Chamber and Dual Chamber Permanent Cardiac Pacemakers

The Centers for Medicare & Medicaid Services (CMS) concluded that implanted permanent cardiac

pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third-degree atrioventricular block. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified conditions are met.

Effective 6/11/13: Fluorodeoxyglucose (FDG) Positron Emission Tomography (PET) for Solid Tumors

The Centers for Medicare & Medicaid Services (CMS) has ended the Coverage with Evidence Development (CED) requirement for FDG PET and PET/CT and PET/MRI for all oncologic indications. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service without the CED requirement.

Effective 5/29/13: Aprepitant for Chemotherapy Induced Emesis

The Centers for Medicare & Medicaid Services (CMS) has included additional anti-cancer chemotherapeutic agents to the list of agents for which the use of the oral antiemetic 3-drug combination of oral aprepitant, an oral 5HT3 antagonist and oral dexamethasone is deemed reasonable and necessary. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for these additional agents.

Effective 4/2/13: Ocular Photodynamic Therapy with Verteporfin for Macular Degeneration

The Centers for Medicare & Medicaid Services (CMS) will expand coverage of Ocular Photodynamic Therapy with verteporfin for “wet” age-related macular edema. CMS is revising the requirements for testing to permit either optical coherence tomography or fluorescein angiography to assess treatment response. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 3/7/13: Positron Emission Tomography (PET) Scans

The Centers for Medicare & Medicaid Services (CMS) will allow local Medicare Administrative Contractors (MACs) to determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for their Food and Drug Administration (FDA) approved labeled indications for oncologic imaging. In accordance with CMS guidance, Solis Health Plans (HMO) will follow these determinations.

Effective 8/2/2012: Autologous Platelet-Rich Plasma (PRP) for Chronic Non-Healing Wounds

The Centers for Medicare & Medicaid Services (CMS) will allow coverage for autologous platelet-rich plasma (PRP) only for the treatment of chronic non-healing diabetic, venous and/or pressure wounds when PRP is

provided under a clinical research study that meets specific requirements. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 6/27/2012: Bariatric Surgery for Treatment of Morbid Obesity

The Centers for Medicare & Medicaid Services (CMS) will allow coverage of stand-alone Laparoscopic Sleeve Gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries when specific conditions are met. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 6/21/2012: Liver Transplants

Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of adult liver transplantation for the following malignancies: (1) extrahepatic unresectable cholangiocarcinoma (CCA); (2) liver metastases due to a neuroendocrine tumor (NET); and, (3) hemangioendothelioma (HAE). In accordance with CMS guidance, Solis Health Plans (HMO) will follow the directions of any issued determinations.

Effective 6/8/2012: Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

The Centers for Medicare & Medicaid Services (CMS) will allow coverage for Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) only when the patient is enrolled in an approved clinical study under Coverage with Evidence Development (CED). Claims should be submitted and reimbursed by the Medicare Administrative Contractor. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 5/1/2012: Transcatheter Aortic Valve Replacement (TAVR)

Transcatheter Aortic Valve Replacement (TAVR) is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when various conditions outlined in the National Coverage Determination (NCD) are met. For indications that are not approved by the FDA, patients must be enrolled in qualifying clinical studies that meet requirements. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service when the specified criteria are met.

Effective 4/30/2012: Extracorporeal Photopheresis

CMS will cover extracorporeal photopheresis for the treatment of Bronchiolitis Obliterans Syndrome (BOS)

following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study that meets specific requirements to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow for this service under the specified conditions.

Effective 11/29/2011: Obesity Therapy

CMS has determined that screening for obesity in older adults along with high intensity behavioral interventions is reasonable and necessary for the prevention or early detection of illness or disability. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow for these preventive services.

Effective 11/8/2011: Intensive Behavioral Therapy for Cardiovascular Disease

CMS now covers intensive behavioral therapy for cardiovascular disease, inclusive of one face-to-face risk reduction visit annually. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow for this preventive service.

Effective 11/8/2011: Screening for Sexually Transmitted Infections (STIs) and High Intensity Behavioral Counseling to Prevent STIs

The evidence is adequate to conclude that screening for chlamydia, gonorrhea, syphilis and hepatitis B, as well as high intensity behavioral counseling (HIBC) to prevent STIs is reasonable and necessary for the prevention or early detection of an illness or disability. Therefore, CMS will cover screening for these indicated STIs with the appropriate laboratory tests when ordered by the primary care physician (PCP) or practitioner. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow for these preventive services.

Effective 10/14/2011: Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse

CMS will now cover an annual alcohol misuse screening and up to four, brief face-to-face behavioral counseling visits in a primary care setting to reduce alcohol misuse. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow for these preventive services.

Effective 10/14/2011: Screening for Depression in Adults

CMS will now cover an annual screening up to 15 minutes for Medicare beneficiaries when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow a screening as a preventive service.

Effective 7/7/2011: Magnetic Resonance Imaging (MRI)

CMS has determined that the evidence is adequate to conclude that magnetic resonance imaging (MRI) improves health outcomes for Medicare beneficiaries with implanted permanent pacemakers (PMs) when the PMs are used according to the FDA-approved labeling for use in an MRI environment. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow the use of MRIs for Medicare Advantage patients with permanent pacemakers.

Effective 6/30/2011: Autologous Cellular Immunotherapy Treatment for Prostate Cancer

CMS has determined that the use of PROVENGE® for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer is reasonable and necessary. In accordance with CMS guidance, Solis Health Plans (HMO) will now allow the use of PROVENGE® for Medicare Advantage patients with these diagnoses.

Effective 5/1/2008: Heart Transplants

Cardiac transplantation is covered under Medicare when performed in a facility which is approved by Medicare as meeting institutional coverage criteria. In accordance with CMS guidance, Solis Health Plans (HMO) will allow for this service under the specified criteria.