Neurology

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- EEG, Noninvasive (MCG ORG: A-0136 AC, 30th Edition)
- OnabotulinumtoxinA (MCG ORG: A-0296 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
95812, 95813	Electroencephalogram (EEG) extended monitoring; 41 to 60 minutes, or greater than 60 minutes
95816, 95819	EEG including recording awake and drowsy, or awake and asleep
95822	EEG recording in coma or sleep only
95824	EEG; cerebral death evaluation only
64616, 64617	Chemodenervation of muscle(s); neck muscle(s) for cervical dystonia, or larynx for laryngeal dystonia
64642-64647	Chemodenervation of one or more extremities and trunk muscles for spasticity and focal dystonia
31573	Laryngoscopy, flexible, with injection into vocal cord(s), therapeutic (e.g., chemodenervation)
J0585	Injection, onabotulinumtoxinA, 1 unit (HCPCS drug code)

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding neurology services, including noninvasive electroencephalography for evaluation of altered neurologic status and seizure disorders, and onabotulinumtoxinA injection for its range of approved neurologic and related indications, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of neurology services and to determine when such services are medically necessary.

Neurologic conditions in the Medicare Advantage population include acute encephalopathy, seizures, and post-arrest coma requiring diagnostic electroencephalography, as well as chronic disabling conditions such as cervical dystonia, chronic migraine, and spasticity that are treated with onabotulinumtoxinA. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary diagnostic testing and therapeutic injection, and inappropriate approval of services performed without adequate indication.

Potential Clinical Harms:

Noninvasive EEG: Inappropriate denial of noninvasive EEG for a change in neurologic status, a comatose patient after cardiac resuscitation, suspected nonconvulsive status epilepticus, or suspected new-onset epilepsy could allow undetected ongoing seizure activity, delayed diagnosis

of treatable encephalopathy, and inaccurate prognostication after cardiac arrest. Missed nonconvulsive status epilepticus in particular carries high morbidity and mortality and is detectable only by EEG.

OnabotulinumtoxinA: Inappropriate denial of onabotulinumtoxinA for an approved indication such as cervical dystonia, blepharospasm, hemifacial spasm, chronic migraine prophylaxis, spasticity, or neurogenic detrusor overactivity could prolong disabling involuntary muscle contraction, pain, functional impairment, and, in the case of bladder dysfunction, upper urinary tract injury. For many of these conditions, onabotulinumtoxinA is the established disease-specific therapy and its denial leaves patients without an effective alternative.

Clinical Benefits:

Noninvasive EEG: MCG criteria provide validated indications drawn from specialty society guidelines and systematic reviews, demonstrating at least moderate certainty of at least moderate net benefit for evaluation of a change in neurologic status, with a systematic review of 165 studies supporting EEG in the management of acute brain injury. By reserving EEG for these specific neurologic presentations, the criteria directly counter the harm of undetected seizure activity and delayed diagnosis identified above while supporting appropriate use of the test.

OnabotulinumtoxinA: MCG criteria specify the approved indications for onabotulinumtoxinA, including achalasia, anal fissure, blepharospasm, cervical dystonia, hemifacial spasm, axillary hyperhidrosis, laryngeal dystonia, chronic migraine prophylaxis, motor tics, overactive bladder, sialorrhea, spasticity, strabismus, upper extremity focal dystonia, and neurogenic detrusor overactivity, each supported by published evidence and, for many indications, Cochrane systematic reviews. By tying therapy to these established indications, the criteria directly address the harm of prolonged disabling symptoms and untreated bladder dysfunction identified above.

Reduction of unwarranted variation and overutilization: MCG criteria also identify the specific conditions and prerequisite findings under which each service is appropriate, reducing repeat or non-indicated EEG studies and onabotulinumtoxinA injection outside approved indications. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current neurologic specialty society guidelines and high-quality evidence, including numerous Cochrane systematic reviews. Use of these criteria ensures patients receive the most clinically appropriate level of care, and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use:

Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for specific neurology services, including noninvasive EEG and onabotulinumtoxinA injection. While Medicare statutes establish the general 'reasonable and necessary' standard, they do not specify the clinical indications and thresholds (e.g., the neurologic presentations warranting EEG, or the specific approved conditions and prerequisite findings for onabotulinumtoxinA) required to distinguish indicated from nonindicated services.

Applicable Medicare References:

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)

- Medicare Benefit Policy Manual, Chapter 14: Medical Devices (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (CMS IOM Publication 100-02)
- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: For noninvasive EEG and onabotulinumtoxinA, no specific NCD or LCD fully establishes clinical thresholds; Original Medicare criteria are not fully established for these services, requiring supplementation. Where applicable LCDs address EEG or onabotulinumtoxinA, MCG criteria are used to supplement and do not replace them.
- Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/search.aspx

Within the above statutes and regulations, coverage criteria for these specific neurology services are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of noninvasive EEG for altered neurologic status, post-arrest coma, suspected seizures, and related neurologic presentations;
- Medical necessity and appropriateness of onabotulinumtoxinA for its approved neurologic and related indications, including the prerequisite clinical findings for each;
- Appropriate clinical setting and expected course for these diagnostic and therapeutic services.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of neurology services. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure diagnostic and therapeutic services are not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Background

EEG, Noninvasive (MCG ORG: A-0136 AC)

Noninvasive (scalp) electroencephalography is an ambulatory diagnostic study indicated for a change in neurologic status (e.g., altered mental status, delirium, encephalopathy), a comatose patient after cardiac resuscitation, differentiation of epileptic from nonepileptic events, suspected or known epilepsy requiring repeat evaluation, suspected new-onset epilepsy or infantile spasms, suspected intracranial infection, disorders of consciousness, and seizures with abnormal mental status or focal deficit. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

OnabotulinumtoxinA (MCG ORG: A-0296 AC)

OnabotulinumtoxinA is a therapeutic injection indicated across a broad range of approved conditions, including achalasia, anal fissure, blepharospasm, cervical dystonia, hemifacial spasm, axillary hyperhidrosis, laryngeal dystonia, chronic migraine prophylaxis, motor tics, overactive bladder, sialorrhea, spasticity, strabismus, upper extremity focal dystonia, and urinary incontinence due to neurogenic detrusor overactivity. Each indication carries its own prerequisite clinical criteria within the guideline.

Evidence Summary

EEG, Noninvasive (MCG ORG: A-0136 AC)

The evidence for the clinical indications in this guideline includes 69 published peer-reviewed articles, 4 specialty society or other evidence-based guidelines, 2 Cochrane systematic reviews, and 2 book sections. Key evidence includes:

- For a change in neurologic status, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review of 165 studies evaluating the use of EEG for management of acute brain injury supports EEG in this setting, including detection of nonconvulsive seizures.
- For a comatose patient after cardiac resuscitation, specialty society guidance supports EEG for seizure detection and neurologic prognostication.
- For suspected epilepsy with a nondiagnostic initial EEG but persistent high clinical suspicion, the criteria support repeat evaluation, and for differentiation of epileptic from nonepileptic events, EEG is supported as the diagnostic standard.

OnabotulinumtoxinA (MCG ORG: A-0296 AC)

The evidence for the clinical indications in this guideline includes 238 published peer-reviewed articles, 16 specialty society or other evidence-based guidelines, and 22 Cochrane systematic reviews. Key evidence includes:

- For the dystonia and spasm indications (e.g., cervical dystonia, blepharospasm, hemifacial spasm, laryngeal dystonia, upper extremity focal dystonia), specialty society guidelines and systematic reviews support onabotulinumtoxinA as established disease-specific therapy.
- For chronic migraine prophylaxis and for spasticity, the criteria are supported by randomized controlled trial evidence and Cochrane systematic reviews demonstrating benefit.
- For overactive bladder and neurogenic detrusor overactivity, evidence supports intradetrusor onabotulinumtoxinA injection to reduce incontinence episodes and protect the upper urinary tract.
- For indications with less certain evidence (e.g., achalasia), the guideline notes that evidence demonstrates a net benefit of less than moderate certainty, and the criteria reflect this in their prerequisite findings.

Rationale (from MCG)

Use of these MCG care guidelines helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate use of neurologic diagnostic testing and therapeutic injection. The evidence-based clinical criteria assist the clinician in deciding when noninvasive EEG is appropriate for a given neurologic presentation, and when onabotulinumtoxinA is appropriate for a specific approved indication based on prerequisite clinical findings. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or

supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition):

- Code of Federal Regulations (CFR): 42 CFR 419.22; 42 CFR 422.101 (noninvasive EEG and onabotulinumtoxinA)
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 6 (Hospital Services Under Part B); Chapter 14 (Medical Devices); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5
- Medicare Coverage Determinations: Medicare Coverage Database: https://www.cms.gov/medicare-coverage-database/search.aspx

References with Citation Summary -- EEG, Noninvasive (MCG ORG: A-0136 AC, 30th Edition)

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