inebilizumab-cdon (Uplizna™)

Medicare Advantage Medical Policy #MA-107
Original Effective Date: 02/01/2026
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Neuromyelitis Optica Spectrum Disorder (NMOSD)

Based on review of available data, the Health Plan may consider inebilizumab-cdon (Uplizna) for the treatment of neuromyelitis optica spectrum disorder (NMOSD) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for inebilizumab-cdon (Uplizna) for the treatment of neuromyelitis optica spectrum disorder (NMOSD) will be considered when the following criteria are met:

Initial Authorization:

- Patient has a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) as evidenced by at least ONE of the following core clinical characteristics:
  - Optic neuritis; OR
  - Acute myelitis; OR
  - Area postrema syndrome (i.e., episode of otherwise unexplained hiccups or nausea and vomiting); OR
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical brain lesions; OR
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions; AND
- Patient is 18 years of age or older; AND
- Patient has a positive anti-aquaporin-4 antibody (AQP4-IgG) serologic test; AND
- Diagnosis of multiple sclerosis has been ruled out; AND
- Patient is NOT receiving a disease modifying multiple sclerosis medication; AND
- Patient has a history of one or more relapses that required rescue therapy during the previous 12 months OR patient has a history of two or more relapses that required rescue therapy during the previous 24 months; AND
- Requested drug is initially dosed as a 300 mg intravenous infusion followed 2 weeks later by a second 300 mg intravenous infusion AND subsequent doses are 300 mg intravenously every 6 months (starting 6 months from the first infusion); AND
- Patient does NOT have active Hepatitis B virus (HBV) as confirmed by positive results for surface antigen [HBsAg] and anti-HBV tests; AND
- If a patient is negative for HBsAg and positive for HB core antibody [HBcAb+] OR patient is a carrier of HBV [HBsAg+]: a liver disease expert has been consulted (and agrees to therapy) prior to therapy with the requested drug; AND

- If the patient has low serum immunoglobulins, an immunology expert has been consulted (and agrees to therapy) prior to therapy with the requested drug; AND
- If a patient has active tuberculosis or positive tuberculosis screening without a history of appropriate treatment: an infectious disease expert has been consulted (and agrees to therapy) prior to therapy with the requested drug; AND
- Any live or live-attenuated immunizations intended to be administered have been administered according to immunization guidelines at least 4 weeks prior to the initiation of the requested drug; AND
- Requested medication is NOT used in combination with satralizumab-mwge (Enspryng), eculizumab (Soliris), or ravulizumab (Ultomiris); AND
- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE other agent for the treatment of NMOSD (e.g., a rituximab product [Rituxan, biosimilars]) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.

Continuation Request:

- Patient has received initial approval for the requested medication from the plan OR has provided documentation of authorization for an active course of treatment from previous health plan; AND
- Patient is NOT receiving a disease modifying multiple sclerosis medication; AND
- Requested drug is dosed as a 300 mg intravenous infusion every 6 months; AND
- Patient does NOT have active Hepatitis B virus (HBV) as confirmed by positive results for surface antigen [HBsAg] and anti-HBV tests; AND
- If a patient is negative for HBsAg and positive for HB core antibody [HBcAb+] OR patient is a carrier of HBV [HBsAg+]: a liver disease expert has been consulted (and agrees to therapy) when continuing therapy with the requested drug; AND
- If a patient has active tuberculosis or positive tuberculosis screening without a history of appropriate treatment: an infectious disease expert has been consulted (and agrees to therapy) when continuing therapy with the requested drug; AND
- Requested medication is NOT used in combination with satralizumab-mwge (Enspryng), eculizumab (Soliris), or ravulizumab (Ultomiris); AND
- Patient has experienced a positive clinical response (e.g., reduction in the frequency of relapse) as attested to by the treating provider.

Immunoglobulin G4-related disease (IgG4-RD)

Based on review of available data, the Health Plan may consider inebilizumab-cdon (Uplizna) for the treatment of Immunoglobulin G4-related disease (IgG4-RD) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for inebilizumab-cdon (Uplizna) for the treatment of Immunoglobulin G4-related disease (IgG4-RD) will be considered when the following criteria are met:

Initial Authorization:

- Patient has a diagnosis of Immunoglobulin G4-related disease (IgG4-RD) as evidenced by a score greater than or equal to 20 according to the 2019 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) Classification criteria; AND
- Other conditions that mimic IgG4-RD have been ruled out (e.g., malignancy, infection, other autoimmune disorders); AND
- Patient is 18 years of age or older; AND
- Patient has a history of involvement of at least 2 or more organs; AND
- Patient has received or is currently receiving systemic corticosteroids for management of an IgG4-RD flare AND meets ONE of the following:
    - The patient has tried and had an inadequate response to systemic corticosteroids (e.g., ≥ 1 flare, new or worsening symptoms, no improvement in organ function, inadequate reduction in organ size); OR
    - There is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
- Patient does NOT have active Hepatitis B virus (HBV) as confirmed by positive results for surface antigen [HBsAg] and anti-HBV tests; AND
- If a patient is negative for HBsAg and positive for HB core antibody [HBcAb+] OR patient is a carrier of HBV [HBsAg+]: a liver disease expert has been consulted (and agrees to therapy) prior to therapy with the requested drug; AND
- If the patient has low serum immunoglobulins, an immunology expert has been consulted (and agrees to therapy) prior to therapy with the requested drug; AND
- If a patient has active tuberculosis or positive tuberculosis screening without a history of appropriate treatment: an infectious disease expert has been consulted (and agrees to therapy) prior to therapy with the requested drug; AND
- Any live or live-attenuated immunizations intended to be administered have been administered according to immunization guidelines at least 4 weeks prior to the initiation of the requested drug; AND
- Requested medication is NOT used in combination with a rituximab product (Rituxan, biosimilars); AND
- Requested drug is initially dosed as a 300 mg intravenous infusion followed 2 weeks later by a second 300 mg intravenous infusion AND subsequent doses are 300 mg intravenously every 6 months (starting 6 months from the first infusion).

Continuation Request:

- Patient has received an initial approval for the requested medication from the plan OR has provided documentation of authorization for an active course of treatment from previous health plan; AND

- Patient has experienced a positive clinical response (e.g., reduction in the corticosteroid dose, reduction in the number of disease flares, increase in the duration of flare-free period, and absence of disease activity) as attested to by the treating provider; AND
- Patient does NOT have active Hepatitis B virus (HBV) as confirmed by positive results for surface antigen [HBsAg] and anti-HBV tests; AND
- If a patient is negative for HBsAg and positive for HB core antibody [HBcAb+] OR patient is a carrier of HBV [HBsAg+]: a liver disease expert has been consulted (and agrees to therapy) when continuing therapy with the requested drug; AND
- If a patient has active tuberculosis or positive tuberculosis screening without a history of appropriate treatment: an infectious disease expert has been consulted (and agrees to therapy) when continuing therapy with the requested drug; AND
- Requested medication is NOT used in combination with a rituximab product (Rituxan, biosimilars); AND
- Requested maintenance dosing does not exceed 300 mg every 6 months.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Health Plan considers the use of inebilizumab-cdon (Uplizna) for NMOSD when the patient DOES NOT have a history of one or more relapses that required rescue therapy during the previous 12 months OR DOES NOT have a history of two or more relapses that required rescue therapy during the previous 24 months to be **not medically necessary.****

Based on review of available data, the Health Plan considers the use of inebilizumab-cdon (Uplizna) for NMOSD when the patient has NOT tried and failed at least ONE other agent for the treatment of NMOSD to be **not medically necessary.****

Based on review of available data, the Health Plan considers the continued use of inebilizumab-cdon (Uplizna) for NMOSD when the patient has NOT experienced a positive clinical response (e.g., reduction in the frequency of relapse) as attested to by the treating provider to be **not medically necessary.****

Based on review of available data, the Health Plan considers the use of inebilizumab-cdon (Uplizna) for IgG4-RD when the patient does NOT have a history of involvement of at least 2 or more organs to be **not medically necessary.****

Based on review of available data, the Health Plan considers the use of inebilizumab-cdon (Uplizna) for IgG4-RD when the patient has NOT experienced an IgG4-RD flare requiring systemic corticosteroids to be **not medically necessary.****

Based on review of available data, the Health Plan considers the continued use of inebilizumab-cdon (Uplizna) for IgG4-RD when the patient has NOT experienced a positive clinical response (e.g., reduction in the corticosteroid dose, reduction in the number of disease flares, increase in the

duration of flare-free period, and absence of disease activity) as attested to by the treating provider to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers the use of inebilizumab-cdon (Uplizna) when the patient selection criteria are not met (with the exception of those considered to be **not medically necessary****) to be **investigational.***

Background/Overview

Uplizna is a CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD). Uplizna has an additional indication for the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adult patients making it the first FDA-approved treatment for IgG4-RD. Uplizna is available in single-dose vials containing 100 mg/10 mL of active ingredient. Before beginning therapy with Uplizna, screenings for hepatitis B virus, tuberculosis, and quantitative serum immunoglobulins should be completed. Based on results of these screenings, the product may be contraindicated, or specialists may need to be consulted prior to beginning Uplizna. Consult the package insert for more details. Prior to each infusion, the provider should determine if there is an active infection (so that treatment can be delayed) and should premedicate with a corticosteroid, an antihistamine, and an antipyretic. Uplizna is administered as an intravenous infusion given initially at a dose of 300 mg followed two weeks later by a second 300 mg dose. Six months after the first infusion, the dosage should be 300 mg given intravenously every 6 months.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

Previously thought to be a subtype of multiple sclerosis, NMOSD is a rare, chronic disorder of the brain and spinal cord dominated by inflammation of the optic nerve and spinal cord. Multiple sclerosis should be ruled out prior to diagnosing NMOSD. Disease modifying multiple sclerosis drugs should not be used concurrently with Enspryng or Uplizna. Disease modifying drugs for the treatment of relapsing forms of multiple sclerosis include oral products such as Gilenya®‡, Mayzent®‡, Tecfidera®‡, Vumerity®‡, Zeposia®‡, Bafiertam™‡, and Aubagio®‡. Other disease modifying medications include Copaxone®‡, Avonex®‡, Rebif®‡, Extavia®‡, Betaseron®‡, Plegridy®‡, Tysabri®‡, Mavenclad®‡, Kesimpta®‡, and Lemtrada®‡. NMOSD often causes significant, permanent damage to vision and/or spinal cord function resulting in blindness or impaired mobility. Most patients with NMOSD experience repeated attacks separated by periods of remission that may last for weeks, months, or years. Over 70% of patients with this disorder produce anti-AQP4 antibodies, which can be a diagnostic factor and may be prognostic of more severe disease. Treatment of acute attacks is typically high-dose intravenous corticosteroids with plasma exchange as a rescue treatment for patients who do not respond adequately to the corticosteroids. Prior to the approval of Enspryng and Uplizna, the mainstay of preventative therapy was Soliris.

Prior to Soliris, the mainstay of therapy was chronic immunosuppression with azathioprine, mycophenolate mofetil, rituximab, methotrexate, mitoxantrone, or oral corticosteroids. The Neuromyelitis Optica Study Group (NEMOS) published revised recommendations for the treatment of NMOSD in 2024. Long term immunotherapy is recommended for patients with AQP4-IgG-positive NMOSD. NEMOS notes the first-choice therapies for the treatment of AQP4-IgG-positive NMOSD are satralizumab-mwge (Enspryng), ecluzimab (Soliris), ravulizumab (Ultomiris), inebilizumab-cdon (Uplizna), and rituximab. The order of preference for these therapies is unclear and further comparative trials and real-world data are needed. The choice of treatment is dependent on several factors, including disease activity and severity, mode and onset of action, effect on autoimmune and other comorbidities, frequency and route of administration, side effect profile, as well as patient and physician preference. In general, if a patient fails a first-choice treatment, another first-choice treatment should be tried; other options include use of a second-choice treatment (azathioprine, mycophenolate mofetil, low-dose oral glucocorticoids) or the addition of a second-choice treatment to the regimen.

Immunoglobulin G4-related disease (IgG4-RD)
IgG4-RD is a rare, progressive, highly destructive, autoimmune, fibroinflammatory disease. It is characterized by elevated serum levels of IgG4 and tumor-like masses. The disease can affect nearly any organ system and typically, multiple organs are affected simultaneously. The most commonly affected organs are pancreas, kidneys, orbital adnexal structures, salivary glands, and retroperitoneum. Diagnosis of IgG4-RD is challenging as there is no single definitive diagnostic test. An accurate diagnosis relies on a combination of clinical and serological features as well as radiological and histological findings. Symptoms related to specific organ involvement mimic other clinical conditions, making misdiagnosis fairly common. The exclusion of other diseases should be incorporated into the diagnostic workup. The American College of Rheumatology (ACR) and the European Alliance of Associations for Rheumatology (EULAR; formerly known as the European League Against Rheumatism) have developed a classification criteria scoring system for identification of the disease. The scoring system is designed to classify patients with IgG4-RD based on a combination of clinical, serologic, radiologic, and histopathologic features. A total score of ≥ 20 points is required for classification as IgG4-RD. The disease course is unpredictable with recurrent flares that cause functional and structural damage in the affected organs. If IgG4-RD is not treated, major organ dysfunction and failure can result. Corticosteroids are the mainstay of treatment for IgG4-RD. Off-label immunosuppressants (e.g., mycophenolate, azathioprine) and rituximab are also used in patients who have an inadequate response or intolerability to steroids or in patients with relapsing disease.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Uplizna is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. Uplizna gained approval for a second indication, the treatment of Immunoglobulin G4-related disease (IgG4-RD) in adults, in April 2025.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Neuromyelitis Optica Spectrum Disorder (NMOSD)

The efficacy of Uplizna for the treatment of NMOSD was established in Study 1, a randomized (3:1), double-blind, placebo-controlled trial that enrolled 213 patients with NMOSD who were anti-AQP4 antibody positive and 17 who were anti-AQP4 antibody negative. Patients met the following eligibility criteria: 1) A history of one or more relapses that required rescue therapy within the year prior to screening, or 2 or more relapses that required rescue therapy in 2 years prior to screening; 2) EDSS score of 7.5 or less. Patients with an EDSS score of 8.0 were eligible if they were deemed capable of participating; 3) Patients were excluded if previously treated with immunosuppressant therapies within an interval specified for each such therapy.

The use of immunosuppressants during the blinded phase of the trial was prohibited.

The use of oral or intravenous corticosteroids during the blinded phase of the trial was prohibited, with the exception of premedication for investigational treatment and treatment for a relapse.

Of the 213 enrolled anti-AQP4 antibody positive patients, a total of 161 were randomized to receive treatment with Uplizna, and 52 were randomized to receive placebo. The mean EDSS score was 4.0. The number of relapses in the two years prior to randomization was 2 or more in 83% of the patients.

Uplizna was administered according to the recommended dosage regimen.

All potential relapses were evaluated by a blinded, independent, adjudication committee, who determined whether the relapse met protocol-defined criteria. Patients who experienced an adjudicated relapse in the randomized-controlled period (RCP), or who completed the Day 197 visit without a relapse, exited the RCP.

The primary efficacy endpoint was the time to the onset of the first adjudicated relapse on or before Day 197.

The time to the first adjudicated relapse was significantly longer in patients treated with Uplizna compared to patients who received placebo (relative risk reduction 73%; hazard ratio: 0.272; $p < 0.0001$). In the anti-AQP4 antibody positive population there was a 77.3% relative reduction (hazard ratio: 0.227, $p < 0.0001$). There was no evidence of a benefit in patients who were anti-AQP4 antibody negative.

Immunoglobulin G4-related disease (IgG4-RD)
The efficacy of Uplizna for the treatment of IgG4-RD was established in Study 2, a randomized, double-blind, multicenter, 52-week placebo-controlled trial that enrolled 135 adult patients who met the following eligibility criteria: 1) Newly diagnosed or recurrent IgG4-RD that required glucocorticoid (GC) treatment at screening; 2) Confirmed history of organ involvement at any time in the course of disease.

The concomitant use of biologic and non-biologic immunosuppressive agents was prohibited during the blinded phase of the trial.

Of the 135 enrolled IgG4-RD patients, 68 patients were randomized to receive Uplizna and 67 were randomized to receive placebo.

Patients were at a uniform 20 mg per day dose of glucocorticoids at the time of randomization and then began a prespecified taper of 5 mg dose every two weeks until discontinuation at the end of 8 weeks. The use of glucocorticoids during the trial was permitted for premedication for investigational treatment, treatment for a relapse and in certain situations other than an IgG4-RD flare.

Uplizna was administered according to the recommended dosage regimen.

Disease flare was defined as new/worsening signs or symptoms that were positively adjudicated and warranted treatment by the investigator. All potential flares were assessed by the investigator and subsequently reviewed by a blinded, independent, adjudication committee, who determined whether the flare met one or more of the protocol-defined, organ-specific flare diagnostic criteria.

The primary efficacy endpoint was the time to First Treated and Adjudication Committee (AC)-determined IgG4-RD flare within the 52-week RCP. The time to the First Treated and AC determined IgG4-RD flare was significantly longer in the Uplizna group, compared with the placebo group. Uplizna reduced the risk of treated and AC-determined IgG4-RD flare by 87%, compared with placebo (hazard ratio: 0.13; $p < 0.0001$).

References

1. Uplizna [package insert]. Viela Bio, Inc. Gaithersburg, Maryland. Updated April 2025.
2. Glisson, CC. Neuromyelitis optica spectrum disorders. UpToDate. August 2019.
3. Kűmpfel T, Giglhuber K, Aktas O, et al. Update on the diagnosis and treatment of neuromyelitis optica spectrum disorders (NMOSD) – revised recommendations of the Neuromyelitis Optica Study Group (NEMOS). Part II: Attack therapy and long-term management. *J Neurol*. 2024;271:141-176
4. Wallace ZS, Naden RP, Chari S Members of the ACR/EULAR IgG4-RD Classification Criteria Working Group, et al. The 2019 American College of Rheumatology/European League Against

Rheumatism classification criteria for IgG4-related disease. *Annals of the Rheumatic Diseases* 2020;79:77-87.

Policy History

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Current Effective Date: 02/01/2026
11/18/2025 UM Committee review and approval. New policy.
Next Scheduled Review Date: 11/2026

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J1823
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

Medicare Advantage Members

Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-bene-help.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.