I. Description:

To define the process by which the clinical criteria utilized in the clinical certification process are established and maintained. This is to ensure that determinations of the medical appropriateness for clinical services are developed with involvement from appropriate healthcare practitioners or prescribers with current knowledge relevant to the criteria or scripts under review and are:

a) based on current evidence-based medical principles; and
b) evaluated at least annually and updated as necessary by the appropriate approval authority and actively practicing physicians, pharmacists and other healthcare practitioners with current, relevant knowledge of the services under review; and
c) accessible to member and providers as appropriate

II. Policy/Criteria:

Clinical Guidelines are documents that define the clinical indications for all services in all programs where eviCore is contracted to provide benefit management and clinical certification for coverage. Clinical guidelines are the basis for the clinical review pathways and decision rules/algorithms, are objective, clinically valid, compatible with established principles of health care and flexible enough to allow deviations from the norm to accommodate individual circumstances and the local delivery system.

Criteria are:

- Written;
- Based on professional practice;
- Evidence-based;
- Applied consistently;
- Reviewed, at a minimum, annually.

III. Definitions

Guidelines: A broadly applicable set of standards, criteria, or protocols used by the organization to guide the clinical processes.

Clinical Pathways: Clinical algorithms based on the criteria, which provide the basis for the scripting, data collection, and decision-making in the care management system.

Clinical Guidelines: The clinical guidelines are comprised of systematically developed criteria statements used in the utilization management review process for eviCore clients.

Program and Health Plan-Specific Processes: The processes below are followed for eviCore Criteria. Program and health plan-specific processes are documented in the Evidence Based Criteria (EBC) Department's standard operating procedures (SOPs).

IV. Responsibility:
Chief Medical Officer (CMO), Associate Chief Medical Officers (ACMO), Executive Medical Director Clinical Content (EMDCC), Medical Advisory Committee (MAC), Clinical Development Lead(s), Compliance Officer, Physician Administration

V. Process:

Clinical guideline development and maintenance is the responsibility of the Clinical Content Team in conjunction with clinical program leaders, eviCore Chief Medical Officer (CMO) and/or the Associate Chief Medical Officers (ACMO) within each benefit management program administered by eviCore (i.e., eviCore Radiology, Cardiology, Sleep, etc.).

A. Guidelines are created for every clinical service managed by eviCore.

B. Guidelines are based on current clinical evidence, clinical practice, and on a working or known diagnosis or common complaint or treatment plan.

C. Guidelines reflect the current evidence and consensus of appropriate diagnostic imaging/treatment option(s) based upon:
   1. Professional Society guidelines and/or appropriateness of criteria
   2. Published peer-reviewed literature
   3. Federal and state regulations
   4. Outside academic and community-based practitioners with specific expertise

D. eviCore healthcare's clinical guidelines are based on the highest quality evidence available. eviCore's guidelines do not differentiate among individuals on the basis of race, ethnicity, gender, or orientation except where supported by high quality clinical evidence.

E. Guidelines are maintained electronically by eviCore's Clinical Content team..

F. Clinical guidelines are published for viewing by members, providers, health plan(s), and any other interested parties on the eviCore healthcare website (eviCore.com).

G. The clinical guidelines specifically related to a request under review must be provided to the physician, facility, and/or member upon request (see policy for *Request for Guidelines UM 0022*).

H. Initial drafts of clinical guidelines for all programs are approved by the Medical Advisory Committee (MAC).

I. MAC-approved clinical guidelines are submitted for review by the applicable health plans and regulatory entities (see 2.D below).

2. Revisions and Amendments

A. Clinical guidelines are reviewed for accuracy and relevance at least annually by the Clinical Programs and MAC.

B. Requests for changes that expand or limit the clinical guidelines will be considered from suggestions or recommendations from the following sources:

   1. Professional society guidelines and appropriateness criteria
   2. Published peer-reviewed literature
   3. Federal and state regulations
   4. Outside academic and community-based practitioners with specific expertise

5. Individual health plans that have determined that the current eviCore guidelines are at variance with the health plan policy: In these scenarios, health plans must provide their own policy to use in place of the eviCore guideline section; these may be applied only for those health plan members.
6. Studies from government agencies [(e.g., the *National Institutes of Health (NIH)*, *Food and Drug Administration (FDA)*]
7. Evaluations performed by independent technology assessment groups
8. Formal change request submitted by any practicing physician supported by new high quality, peer reviewed evidence through peer consultation or web submission on eviCore.com.

C. The CMO and/or ACMOs and MAC must be satisfied that any change is supported by sound medical evidence from one or more of the sources noted above.

D. Minor amendments that are not substantive in nature including corrections of typing errors, clarifications of existing criteria, and changes in format will be reviewed in an expedited MAC, rather than full MAC review. Please see MAC Charter for additional detail. Substantive amendments can be implemented with the approval of the CMO prior to the next scheduled MAC committee meeting when the modification expands the criteria or the restriction is considered integral to the consistency of the criteria. In these instances, an ad hoc MAC review will be requested.

3. Approvals

A. All newly developed clinical guidelines and/or revisions are to be reviewed internally and approved as indicated by:
   1. The CMO
   2. Executive Medical Director, Clinical Content (can approve policies on behalf of the CMO)
   3. Majority of voting members of the MAC
   4. Outside physicians/practitioners with specific expertise
   5. Health plan Medical Directors and/or Clinical Policy Committees (active approval not required unless otherwise indicated in client contract)
   6. Appropriate regulatory entities

   Clinical guidelines that are adopted for use by a health plan that are externally created, such as commercial criteria (i.e., *Interqual* or *MCG™* (formerly *Milliman Care Guidelines*) and health plan policy will be reviewed and acknowledged by the CMO, EMDCC, MAC Chair, or MAC Vice Chair.

B. Clinical guideline revisions will be forwarded to the Client Experience Manager and/or designee who will forward them to the health plan for review and approval.

C. eviCore will provide clients with ninety (90) days' notice of material changes to the clinical guidelines. In addition, these changes will be posted to the eviCore website (eviCore.com) for the full 90 days.

   1. The posted guideline updates will be implemented for all clients on the stated effective dates. All downstream operations will reflect these changes, including relevant clinical pathways.

   2. Clients may request a variance from any of the presented material changes during this 90-day posting period. Clients will notify their applicable Client Experience Manager of any requested variances and provide their own policy(ies) to support the variance(s).

   3. Implementation of client-requested variances may take up to 90 days beyond the original effective date. If the clients' internal committees cannot review the posted guidelines within the 90-day posting period, eviCore will proceed with implementation of the stated effective date to maintain compliance. Client may also request variances to the guidelines after the 90-day posting period.

D. Throughout any given year, new evidence/recommendations are published by clinical/medical society, working group, institution, or bodies of experts (for example: NCCN, ASTRO, NASS).

1. Such updates that are “positive” (expand the coverage for patients) and impactful (high volume of cases impacted) may be implemented by eviCore within thirty (30) days.
2. Evidence updates in peer-reviewed published journal articles that are not published as part of an entity mentioned above will be incorporated into eviCore’s usual guideline revision process.
3. eviCore will notify clients of “positive” changes at least fourteen (14) business days prior the effective date.
4. Positive changes will be implemented for all clients on the stated effective date; all downstream operations will reflect these changes, including relevant clinical pathways.
5. Clients may request that the positive change not be applied to their patient population.

E. In the event that approval is not received from the health plan, follow-up will be made to attempt to obtain approval. If the health plan does not provide feedback within the agreed upon review period, eviCore reserves the right to implement the guideline changes to eviCore guidelines.

4. Implementation

A. Approved versions of eviCore clinical guidelines are posted internally, published to the applicable website, and distributed to interested health plans and applicable regulatory agencies.

B. A new version of eviCore clinical guidelines will be released to the health plans and applicable regulatory agencies after each annual criteria review.

1. Clinical guideline versions released in 20XX are labeled with effective dates.
2. Interval versions reflecting changes approved as described herein may be released at the discretion of the CMO, or designee, if the amendments result in a material change in precertification policy.
3. Appropriate copyright notices [e.g., National Comprehensive Cancer Network (NCCN), American Medical Association (AMA), etc.] are noted in the respective criteria document(s).
4. The Clinical Integration Department will be responsible for providing criteria documents for distribution to the health plans via eviCore’s Client Management team..
5. All clinical guidelines will have an effective date and upon that effective date, being reached will supersede all previous versions.
6. Computer applications utilizing the clinical guidelines are updated to reflect the current criteria.

5. Integration

A. Changes to clinical pathways/algorithms are managed by the Clinical Integration Team. Clinical guidelines approved for use are forwarded to the Clinical Integration Lead or designated ACMO who designs automated decision pathways/algorithms for the clinical data collection application.

1. Clinical pathways are designed/amended by the ACMO(s) or designees in collaboration with Program Operations and programming personnel.

B. Pathway/Algorithm testing

1. System changes to the pathways are reviewed and tested by the ACMO(s) and/or

designees to verify that they are functioning correctly and are consistent with the criteria.

2. When testing of the pathway is complete, it is promoted into the live environment.

C. Communication of changes
When changes to the clinical guidelines and pathways/algorithms are made, they are communicated to all applicable clinical staff by the ACMO(s) or designee. *Retention:*

A. Archived copies of previous versions of all eviCore and health-plan specific utilization clinical guidelines for all programs are maintained in the eviCore systems to be retrieved and released as required.

Statement of Health Equity:
It is the responsibility of health care institutions to support patient care in a manner that does not discriminate based on biological and/or social demographics, including income, race, ethnicity, age, and gender markers. eviCore's role in promoting health equity is centered primarily on our use of evidence-based guidelines in utilization management. The guidelines are applied equitably for all patients, while taking into account individual clinical scenarios that indicate the need for unique care protocols.

eviCore minimizes bias through the application of evidence-based clinical guidelines that standardize decisions across populations, except in scenarios where evidence suggests the need for unique imaging, tests, or procedure protocols. Moreover, eviCore acknowledges that the clinical evidence upon which the guidelines are based may not fully represent all ethnic and racial groups. However, as new evidence becomes available in peer-reviewed literature and/or by nationally recognized societies, eviCore updates the clinical guidelines to reflect the new evidence. eviCore welcomes input from all external stakeholders on opportunities to further reduce bias in the clinical guidelines.

The terms "male" and "female" used in guidelines refer to anatomic-specific diseases and disease predispositions associated with individuals' sex assigned at birth rather than their gender identity. It should be noted that gender identity and anatomic-specific diseases, as well as, disease predispositions are not always linked. As such, guidelines should be applied to the individual's corresponding known or suspected anatomic-specific disease or disease predisposition. As such, the term male utilized in guidelines can also include transgender female, gender "X", and "Not specified". The term female utilized in guidelines can also include transgender male, gender "X", and "Not specified".

At eviCore, we believe that it is important to understand how all individuals, including those who are gender-diverse, choose to identify themselves. To ensure that gender-diverse individuals are treated with respect and that decisions impacting their healthcare are made correctly and with sensitivity, eviCore recognizes all individuals with the following gender marker options: Male, Female, Transgender male, Transgender female, "X", and "Not specified".

Medicare Addendum

In accordance with changes in coverage requirements as set forth by CMS (Center for Medicare and Medicaid Services) or its intermediaries for Medicare members, Medicare criteria will be reviewed and implemented as set forth below. This may include, but is not limited to:

- CMS Coverage Listserv weekly notifications for national coverage updates, such as national coverage analyses (NCAs) and national coverage determinations (NCDs), CMS announcements of new topics opened for national decision, posting of decision memos, and posting of final technology assessment (TA) reports, program memorandums, program transmittals, or written CMS instructions or regulations regarding Part C of the Medicare program

- Part B Carrier and MAC coverage Listserv alerts from applicable intermediaries that identify changes in local coverage decisions, (LCDs) or other changes in coverage.

1. The eviCore CMO, ACMO(s) or designee, and Clinical Content designees will receive and review all applicable email and listserv updates for NCDs and LCDs from all regional carriers and intermediaries.
2. The Clinical Content designees are responsible for communicating relevant LCDs and NCDs to the ACMO(s). Notification will occur within two (2) business days and a notice will be posted on the physician portal regarding the changes with links to the revised policy document(s).
3. Changes to the Medicare criteria that are made as a result of changes in National or Local policy will be implemented into the published criteria documents (see Radiation Therapy exception) within fourteen (14) calendar days.
4. Pathway revisions and criteria changes that are the result of changes in Medicare policy will be implemented into the appropriate clinical platform in the next release cycle.
5. Within thirty (30) days following the date of any LCD or NCD change, the Clinical Content designee will verify that the change has been implemented according to the applicable Medicare policy change and report any compliance issues to the CMO, ACMO(s) or designees.
6. If during internal case audit or external health plan or regulatory audit, it is identified that a service request decision was processed outside of the current coverage policy guidelines effective dates, the following process will be followed:

    - If the audit determined that the request should have been reviewed using new and/or updated coverage guidelines, the case will be referred, along with the internal/external audit review, to the Physician Administration department who will route the request to the appropriate Medical Director for reprocessing to include reversing the decision, where applicable.

CMS Coverage Hierarchy: Medicare Advantage Medical Policy Development

Medicare Advantage medical policies identify the clinical criteria for determining when medical services are considered 'reasonable and necessary' (medically necessary). Medicare Advantage plans are required by CMS to provide the same medical benefits to Medicare Advantage members as original Medicare.

Medicare Advantage plans must comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare laws. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. When coverage criteria are not fully established in Medicare statute, regulation, NCD, or LCD, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature.

Coverage criteria are not fully established when:

1) additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently;

2) NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD;

3) or there is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria. When additional, unspecified criteria are needed to interpret or supplement general provisions, the MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

If there is no applicable NCD, LCD, or LCA (used in concert with an LCD), for the service under review, then other evidence-based criteria may be applied. In addition, each member's unique clinical situation is considered in conjunction with current CMS guidelines.

Guideline Hierarchy

The following hierarchy is used to determine Medicare Advantage Medical Policy:

- ***CMS Coverage Manuals or other CMS-Based Resource:***
  - Coverage provisions in interpretive manuals are instructions that are used to further define when and under what circumstances items or services may be covered (or not covered).
- ***National Coverage Determinations (NCD)***:
  - For some services, procedures, and technologies, CMS has developed a NCD, which is to be applied on a national basis for all Medicare beneficiaries. Once published in a CMS program instruction, the NCD is binding on all Medicare Advantage plans.
- ***Local Coverage Determinations (LCD), Articles (LCA), and other contractor-based bulletins***:
  - An NCD sets forth the extent to which Medicare will cover specific services, procedures, or technologies on a national basis. If an NCD does not specifically exclude/limit an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, then an LCD may be in place to offer guidance, and used to adjudicate the organization determination decision.
  - For services or items that have an applicable NCD and LCD, the reviewer must:
    - First, review the NCD to ensure that all requirements are met. If the NCD requirements are not met, deny the request using the NCD, and cite the NCD (i.e., stop reviewing at this point and do not apply the LCD);
      - If the applicable NCD does not contain sufficient detail regarding medical necessity criteria for a specific service and indication to render a decision, review the LCD to ensure requirements are met.
    - If the NCD requirements are met, approve the case, (i.e. stop reviewing and do not apply the LCD). If the NCD does not contain relevant medical necessity criteria for the service and indication, move to the next step.
    - Second, review the LCD to ensure the requirements are met.
      - In a singular written denial rationale, for a scenario where there is both an NCD and LCD for the service under review, the reviewer would cite the LCD if the LCD is the basis of the denial (i.e., insufficient information in the NCD to render a decision).
  - If an LCD is applicable to the organization determination under review, the review is completed using an LCD from the MAC where the service is being performed (place of service).
  - Local Coverage Articles (LCA) can be used in conjunction with LCDs.
  - ****Laboratory Management ONLY**: If appropriate LCDs do not exist in the given MAC jurisdiction, identify any policies from the *MolDX Program* (Palmetto GBA) that apply to the test.
- ***Health Plan Objective, Evidence based Medical Policies***:
  - When coverage criteria are not fully established in Medicare statute, regulation, NCD, LCD, CMS guidelines allow for a Medicare Advantage Organization (MAO) to make its own internal coverage criteria. In this case, eviCore's evidence-based guidelines or the appropriate alternative guideline utilized by a program/health plan in place of eviCore's guidelines would be used for case adjudication. In these situations, the MAO may apply the health plan's Medical Policy criteria to the services under review. The health plan's medical policies are developed following an objective, evidence-based process based on scientific evidence, generally accepted and current standards of medical practice, and authoritative clinical practice guidelines.

- ***MCG™ (formerly Milliman Care Guidelines), Interqual, or other nationally recognized guidelines****:*
    - If no policy criteria are available within an NCD, LCD, coverage manual, or existing medical policy for the services in question, *MCG™*, *Interqual* or other nationally recognized guidelines may be applied.

**The Laboratory Management program utilizes the *MolDX Program* administered by the Palmetto GBA MAC for the development of LCDs for genetic tests.

Note: Where a Medicare Administrative Contractor (MAC) has adopted the Palmetto GBA MolDX® Program's criteria for the LCDs governing molecular and genomic tests within their jurisdiction, eviCore's Laboratory Management program will follow the MolDX criteria published by the MACs for those jurisdictions.

42 CFR 422.101 Requirements relating to basic benefits.

Except as specified in § 422.318 (for entitlement that begins or ends during a hospital stay) and § 422.320 (with respect to hospice care), each MA organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with—

(1) CMS's national coverage determinations;

(2) General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. For example, this includes payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a)(3).

(3) Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:

(i) An MA organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in § 422.254(a)(1), which is 60 days before the date bid amounts are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to MA enrollees.

(ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the MA organization of its approval or denial of the selected uniform local coverage policy or policies.

(4) Instead of applying rules in paragraph (b)(3)(ii) of this section, and to the extent it exercises this

option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.

(5) If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.

(6) MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.

(i) Coverage criteria not fully established. Coverage criteria are not fully established when:

(A) additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. The MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;

(B) NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or

(C) There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.

(ii) Publicly accessible. For internal coverage policies, the MA organization must provide in a publicly accessible way the following:

(A) The internal coverage criteria in use and a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;

(B) A list of the sources of such evidence; and

(C) An explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. When coverage criteria are not fully established as described in paragraph (6)(i)(A), the MA organization must identify the general provisions that are being supplemented or interpreted and explain how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

(c) Medical necessity determinations and special coverage provisions—

(1) Medical necessity determinations.

(i) MA organizations must make medical necessity determinations based on all of the following:

(A) Coverage and benefit criteria as specified at paragraphs (b) and (c) of this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) or (c) of this section.

(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.

(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.

(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

(ii) [Reserved]

Medicaid Hierarchy and Application of Medicaid Hierarchy in Adjudication of Clinical Cases

Medicaid Hierarchy

1) State-specific Medicaid policy
2) eviCore's evidence-based guidelines or the appropriate alternative guideline utilized by a program/health plan in place of eviCore's guidelines (i.e., MCG or health-plan specific policy as appropriate)
3) For members under 21 years of age, Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines should also be reviewed for applicability and coverage determination and applied.

Application of Medicaid Policy:
As the degree of specificity in state Medicaid policies vary significantly, detailed guidance is needed to inform reviewers regarding the adjudication of Medicaid clinical cases for utilization management. The purpose of this section is to ensure consistent application and citation of criteria for the adjudication of Medicaid cases. The state policy should be utilized for adjudication whenever possible and other guidelines should only be utilized when insufficient clinical criteria are available to make a decision. In general, application of medical necessity criteria should never be more restrictive than the state Medicaid policy. The state Medicaid policy should always be reviewed first to determine if the information provided is instructive to the clinical case at hand. For the purpose of this policy, sufficient clinical criteria to render a medical necessity decision is defined as the presence of a state Medicaid policy that addresses the service/procedure/test/equipment and the member condition (indication) and supplies sufficient clinically relevant detail on the to be instructive to the case. Please see the numbered items below for specific guidance.

1) **State Medicaid policy addresses clinical scenario: (service/procedure/test/equipment AND member condition AND Medical Necessity criteria):**
    a. Utilize and cite Medicaid policy for decision-making.
    b. If medical necessity criteria are present in the state policy, but are limited or less detailed than eviCore or alternative guideline above, the state policy would still be

applied and cited, as this would be considered sufficient information to render a decision.

2) **State Medicaid Policy addresses service/procedure/test/equipment, but does NOT cover member condition in question or medical necessity criteria for this indication and does not contain relevant clinical information to be instructive to the case/clinical scenario:** (For example, if the state specific policy addressed the use of continuous positive airway pressure for obstructive sleep apnea (OSA), but not for central sleep apnea):
    a. Utilize and cite eviCore guidelines or alternative guidelines, above as appropriate.

3) **State policy exists for service/procedure/test/equipment AND member condition but NO medical necessity criteria exist for this indication. The state policy would still be instructive to the case clinical scenario :** (For example, if the state specific policy listed obstructive sleep apnea as an indication for continuous positive airway pressure but did not include detailed medical necessity criteria):
    a. Utilize and cite Medicaid policy for decision-making.
4) If no clinical information is provided with a request, the above hierarchy is still applied. If there is an applicable state-specific Medicaid policy, the Medicaid policy would be utilized and cited to request clinical information/documentation. If there is no applicable state-specific Medicaid policy, eviCore policy or proprietary policy can be utilized and cited.

There may be variances in eviCore clients' state Medicaid contracts with a state Medicaid entity. For each Medicaid contracted client implementation, the client will be responsible for providing eviCore with their specific contract currently active with a state Medicaid entity. Once received eviCore will review the client's state Medicaid contract in order to understand specific contract requirements, which may affect the hierarchy of review for Medicaid requests. The scope of this policy is to outline the default order in which policy sources will be used during a delegated medical necessity determination. The Medicaid hierarchy outlined here may be superseded by Plan- and State-specific Hierarchy policies, where applicable.

Medicare/Medicaid Dual Membership Application

Some individuals are dually enrolled in Medicare and Medicaid. For these cases, the following hierarchy should be applied:

1) CMS Coverage Manuals
2) National Coverage Determinations (NCD)
3) Local Coverage Determinations (LCD)
4) Local Coverage Articles (LCA) – when used in conjunction with an LCD
5) Apply Medicaid Hierarchy as outlined above

State Specific Requirements:

Arizona	**Arizona Health Care Cost Containment System (AHCCCS) Medical Policy Manual, Chapter 1020 Medical Management Scope and Content** **III. Policy** **G. Clinical Practice Guidelines:** 1. Contractors shall develop or adopt and disseminate practice guidelines for physical and behavioral health services that: a. Are based on valid and reliable clinical evidence or a consensus of health care

	professionals in that field as specified in 42 CFR 457.1233(c) and 42 CFR 438.236(b)(1), b. Have considered the needs of the Contractor's members as specified in 42 CFR 457.1233(c) and 42 CFR 438.236(b)(2), c. Are adopted in consultation with contracted health care professionals and National Practice Guidelines as specified in42 CFR 457.1233(c) and 42 CFR 438.236(b)(3), or d. Are developed in consultation with health care professionals and include a thorough review of peer-reviewed articles in medical journals published in the United States when national practice guidelines are not available, e. Are disseminated by the Contractor to all affected providers and, upon request, to members/Health Care Decision Makers and potential members, and f. Provide a basis for consistent decisions for utilization management, member education, coverage of services, and any other areas to which the guidelines apply as specified in 42 CFR 457.1233(c) and 42 CFR 438.236(d). 2. Contractors shall annually evaluate the practice guidelines through a MM Committee to determine if the guidelines remain applicable, represent the best practice standards, and reflect current medical standards as specified in 42 CFR 457.1233(c) and 42 CFR 438.236(b)(4). 3. Contractors shall document the review and adoption of the practice guidelines as well as the evaluation of efficacy of the guidelines in the MM Committee meeting minutes.
Arkansas	**Arkansas Code 23-99-1104 Disclosure Required:** (a)(1) A utilization review entity shall disclose all of its prior authorization requirements and restrictions, including any written clinical criteria, in a publicly accessible manner on its website. (2) The information described in subdivision (a) (1) of this section shall be explained in detail and in clear and ordinary terms. (3)(A) Utilization review entities that have, by contract with vendors or third-party administrators, agreed to use licensed, proprietary, or copyrighted protected clinical criteria from the vendors or administrators, may satisfy the disclosure requirement under subdivision (a)(1) of this section by making all relevant proprietary clinical criteria available to a healthcare provider that submits a prior authorization request to the utilization review entity through a secured link on the utilization review entity's website that is accessible to the healthcare provider from the public part of its website as long as any link or access restrictions to the information do not cause any delay to the healthcare provider. (B) For out-of-network providers, a utilization review entity may meet the requirements of this subdivision (a)(3) by: (i) Providing the healthcare provider with temporary electronic access in a timely manner to a secure site to review copyright protected clinical criteria; or (ii) Disclosing copyright-protected clinical criteria in a timely manner to a healthcare provider through other electronic or telephonic means. (b) Before a utilization review entity implements a new or amended prior authorization requirement or restriction as described in subdivision (a)(1) of this section, the utilization review entity shall update its website to reflect the new or amended requirement or restriction. (c) Before implementing a new or amended prior authorization requirement or restriction, a utilization review entity shall provide contracted healthcare providers written notice of the new or amended requirement or restriction at least sixty (60) days before implementation of the new or amended requirement or restriction. Enacted 3/20/17.
Connecticut	For members subject to **Connecticut § 38a-591d(e)(1)(F) (Effective January 1, 2017):** (F)(i)(I) A copy of the specific rule, guideline, protocol or other similar criterion the health carrier relied upon to make the adverse determination, or (II) a statement that a specific rule, guideline, protocol or other similar criterion of the health carrier was relied upon to make the adverse determination and that a copy of such rule, guideline, protocol or other similar criterion will be provided to the covered person free of charge upon request, with instructions

	for requesting such copy, and (ii) the links to such rule, guideline, protocol or other similar criterion on such health carrier's Internet web site.
Delaware	**18 De. C. § 3582 .** Disclosure and review of pre-authorization requirements. (a) A utilization review entity shall make any current pre-authorization requirements and restrictions readily accessible on its website and in written or electronic form upon request for covered persons, health-care providers, and others with access to the website. Information from a utilization review entity that is not an insurer, health-benefit plan, or health-service corporation shall make this information available at an electronic pre-authorization portal that is accessible in real time. Requirements shall be described in detail but also in clear, easily understandable language. Clinical criteria shall be described in language easily understandable by a health-care provider practicing in the same clinical area. **ACDE Pro Forma MSA 2023 Effective 1.1.2023** 3.14.2 Written Member Material Guidelines 3.14.2.1 The Contractor shall ensure that all member materials use person-centered and easily understood language and format. 3.14.2.2 All written member materials must be worded at or below a sixth grade reading level, unless otherwise approved in writing by the State.
Illinois	**HB711 (effective 1/1/2022): Impacts – Commercial Fully Insured, Commercial Self-Insured Non-ERISA, Managed Medicaid (use decision timeframes that is more stringent from the Medicaid contract), Fee-For-Service (FFS) Medicaid, and Children's Health Insurance Plan (CHIP)** New and Revised Prior Authorization Requirements If a health insurance issuer intends to implement a new prior authorization requirement or restriction or amend an existing requirement or restriction, the health insurance issuer must provide contracted health care professionals and contracted health care providers of enrollees written notice of the new or amended requirement or amendment no less than 60 days before the requirement or restriction is implemented. The written notice may be provided in an electronic format, including e-mail or facsimile if the health care professional or health care provider has agreed in advance to receive these notices electronically. The health insurance issuer must ensure that the new or amended requirement is not implemented unless the health insurance issuer's or its contracted URO's website has been updated to reflect the new or amended requirement or restriction.
Indiana	HB1143 (effective 1/1/2020) A health plan shall provide notice to participating providers of a new prior authorization requirement not less than forty-five (45) days before the new requirement takes effect.
Kentucky	**KRS 304.17A-603 (2)** (2) An insurer shall maintain written procedures for: (a) Determining whether a requested service, treatment, drug, or device is covered under the terms of a covered person's health benefit plan; (b) Making utilization review determinations; and (c) Notifying covered persons, authorized persons, and providers acting on behalf of covered persons of its determinations. **KRS 304.17A-603 (4) (a) & (b):** (4) (a) If an insurer requires preauthorization to be obtained for a service to be covered, the insurer shall maintain information on its publicly accessible Web site about the list of services and codes for which preauthorization is required. The Web site shall indicate, for each service required to be preauthorized: 1. When preauthorization was required, including the effective date or dates and the

	termination date or dates, if applicable; 2. The date the requirement was listed on the insurer's Web site; and 3. Where applicable, the date that preauthorization was removed. (b) An insurer shall maintain a complete list of services for which preauthorization is required, including for all services where preauthorization is performed by an entity under contract with the insurer.
Louisiana	**LOUISIANA MEDICAID MANAGED CARE ORGANIZATION** **Attachment B - STATEMENT OF WORK** The MCO must identify the source of the medical management criteria used for the review of service authorization requests, including but not limited to: 8.1.6.1. The vendor must be identified if the criteria was purchased; 8.1.6.2. The association or society must be identified if the criteria are developed/recommended or endorsed by a national or state health care provider; 8.1.6.3. The guideline source must be identified if the criteria are based on national best practice guidelines; and 8.1.6.4. The individuals who will make medical necessity determinations must be identified if the criteria are based on the medical training, qualifications, and experience of the MCO medical director or other qualified and trained professionals.
Minnesota	**62M.10 ACCESSIBILITY AND ON-SITE REVIEW PROCEDURES** Subd. 7.**Availability of criteria:** (a) For utilization review determinations other than prior authorization, a utilization review organization shall, upon request, provide to an enrollee, a provider, and the commissioner of commerce the criteria used to determine the medical necessity, appropriateness, and efficacy of a procedure or service and identify the database, professional treatment guideline, or other basis for the criteria. (b) For prior authorization determinations, a utilization review organization must submit the organization's current prior authorization requirements and restrictions, including written, evidence-based, clinical criteria used to make an authorization or adverse determination, to all health plan companies for which the organization performs utilization review. A health plan company must post on its public website the prior authorization requirements and restrictions of any utilization review organization that performs utilization review for the health plan company. These prior authorization requirements and restrictions must be detailed and written in language that is easily understandable to providers. Subd. 8. **Notice: new prior authorization requirements or restrictions; change to existing requirement or restriction.** (a) Before a utilization review organization may implement a new prior authorization requirement or restriction or amend an existing prior authorization requirement or restriction, the utilization review organization must submit the new or amended requirement or restriction to all health plan companies for which the organization performs utilization review. A health plan company must post on its website the new or amended requirement or restriction. (b) At least 45 days before a new prior authorization requirement or restriction or an amended existing prior authorization requirement or restriction is implemented, the utilization review organization, health plan company, or claims administrator must provide written or electronic notice of the new or amended requirement or restriction to all Minnesota-based, in-network attending health care professionals who are subject to the prior authorization requirements and restrictions. **62M.17 CONTINUITY OF CARE; PRIOR AUTHORIZATIONS**

	Subd. 2.Effect of change in prior authorization clinical criteria (a) If, during a plan year, a utilization review organization changes coverage terms for a health care service or the clinical criteria used to conduct prior authorizations for a health care service, the change in coverage terms or change in clinical criteria shall not apply until the next plan year for any enrollee who received prior authorization for a health care service using the coverage terms or clinical criteria in effect before the effective date of the change. (b) Paragraph (a) does not apply if a utilization review organization changes coverage terms for a drug or device that has been deemed unsafe by the United States Food and Drug Administration (FDA); that has been withdrawn by either the FDA or the product manufacturer; or when an independent source of research, clinical guidelines, or evidence-based standards has issued drug- or device-specific warnings or recommended changes in drug or device usage. (c) Paragraph (a) does not apply if a utilization review organization changes coverage terms for a service or the clinical criteria used to conduct prior authorizations for a service when an independent source of research, clinical guidelines, or evidence-based standards has recommended changes in usage of the service for reasons related to patient harm. (d) Paragraph (a) does not apply if a utilization review organization removes a brand name drug from its formulary or places a brand name drug in a benefit category that increases the enrollee's cost, provided the utilization review organization (1) adds to its formulary a generic or multisource brand name drug rated as therapeutically equivalent according to the FDA Orange Book, or a biologic drug rated as interchangeable according to the FDA Purple Book, at a lower cost to the enrollee, and (2) provides at least a 60-day notice to prescribers, pharmacists, and affected enrollees.
Missouri	**SB514** (effective 1/1/20) (376.1372) **Notification of changes to prior authorization requirements**: Health carriers and utilization review entities shall provide participating providers with written or electronic notice of a new or amended requirement not less than sixty (60) days prior to implementing the new requirement or restriction. **SB514** (effective 1/1/20) (376.1372) **Criteria Posted on Website or Portal**: Prior authorization requirements and restrictions, including clinical review criteria, must be readily accessible on the health carrier or utilization review entity's website or provider portal. Requirements, including step therapy protocols, shall be described in detail.
New Hampshire	**State of New Hampshire Medicaid Care Management Services Contract** **Exhibit A- Scope of Services** 4.8 Utilization Management 4.8.2.4 The MCO may substitute generally recognized, accepted guidelines to replace the U.S. Preventive Services Task Force and AAP Bright Futures program requirements, provided that the MCO meets all other Practice Guidelines requirements indicated within this Section 4.8.2 (Practice Guidelines and Standards) of the Agreement and that such substitution is reviewed by DHHS prior to implementation.
New Jersey	Changes to the utilization review guidelines posted on the eviCore website are posted 30 days prior to implementation.
New York	**NY Public Health (PBH) § 4902** – Utilization Review Program Standards. 3. When establishing a step therapy protocol, a utilization review agent shall utilize recognized evidence-based and peer reviewed clinical review criteria that takes into account the needs of atypical patient populations and diagnoses as well when establishing the clinical review

	criteria. **NY Insurance Law §4902** – Utilization Review Program Standards (a) Each utilization review agent shall adhere to utilization review program standards consistent with the provisions of this title which shall, at a minimum, include: 10. When establishing a step therapy protocol, a utilization review agent shall utilize recognized evidence-based and peer reviewed clinical review criteria that also takes into account the needs of atypical patient populations and diagnoses when establishing the clinical review criteria.
Ohio	**The Ohio Department of Medicaid; Ohio Medicaid Provider Agreement for Managed Care Organization** Appendix A - General Requirements 7. MCO Website Requirements. a. General xii. The MCO must post on its website the MCO's criteria for medical necessity determinations for services requiring authorization. In accordance with 42 CFR 438.915(a), the MCO must provide a hard copy of the MCO's medical necessity criteria to providers and members upon request. Appendix B – Coverage and Services 5. Utilization Management Program. b. Policies and Procedures. iv. The MCO must notify network and out-of-network providers of clinical coverage policies. The communication must include an outline or a summary specifying the changes and their impact on specific providers receiving the policy changes. Changes to policies require 30 days advance notice. Provider notifications must meet the requirements in Appendix A, General Requirements. 6. Coverage Requirements. a. Medical Necessity Criteria. i. Pursuant to OAC rule 5160-26-03, the MCO's coverage requirements and decisions must be based on the coverage and medical necessity criteria published in OAC Chapter 5160 and practice guidelines as specified in OAC rule 5160-26-05.1. ii. The MCO must have objective, written criteria based on sound clinical evidence to make medical necessity and utilization decisions. The MCO must involve appropriate providers in the development, adoption, and review of medical necessity criteria. The MCO's written criteria must meet NCQA standards and must specify procedures for appropriately applying the criteria. iii. The MCO must use ODM-developed medical necessity criteria where it exists. In the absence of ODM-developed medical necessity criteria, the MCO must use clinically-accepted, evidence-informed medical necessity criteria (e.g., InterQual®, MCG®, and ASAM) as approved by ODM. iv. In the absence of ODM-developed medical necessity criteria or ODM-approved, clinically-accepted, evidence-informed medical necessity criteria, the MCO's adaptation or development of medical necessity criteria must be based upon evaluated, peer reviewed medical literature published in the United States. 1. Peer reviewed medical literature must include investigations that have been reproduced by non-affiliated authoritative sources. 2. The literature must also include positive endorsements by national medical bodies or panels regarding scientific efficacy and rationale that is based upon well-designed research and endorsements by national medical bodies or panels regarding scientific efficacy and rationale. v. When applying coverage policies and medical necessity criteria, the MCO must consider individual member needs and an assessment of the local delivery system.

Pennsylvania	**PA HealthChoices (HC) Agreement and Exhibits (Sept 2022)** Exhibit H Prior Authorization Guidelines for Participating Managed Care Organization in the HealthChoices Program B. Guidelines for Review 2(b) All criteria must be submitted to the Department for evaluation and approval prior to implementation (c)For Delegates, if the criteria being used are: • Purchased and licensed, the Delegate must identify the vendor; • Developed/recommended/endorsed by a national or state health care provider association or society, the Delegate must identify the associate or society; • Based on national best practice guidelines, the Delegate must identify the source of those guidelines; • Based on the medical training, qualifications, and experience of the Delegate's Medical Director or other qualified and trained practitioners, the Delegate must identify the individuals who will determine if the service or benefit is Medical Necessary.
Rhode Island	In accordance with **Office of the Health Insurance Commissioner (OHIC) (27-18.9(b)(7)):** The review agent using clinical criteria and medical judgment in making utilization review decisions shall comply with the following: i. The requirement that each review agent shall provide its clinical criteria to OHIC upon request; ii. Provide and use written clinical criteria and review procedures established according to nationally accepted standards, evidenced based medicine and protocols that are periodically evaluated and updated or other reasonable standards required by the commissioner; iii. Established and employ a process to incorporate and consider local variations to national standards and criteria identified herein including without limitations, a process to incorporate input from local participating providers; and iv. Updated description of clinical decision criteria to be available to beneficiaries, providers, and the office upon request and readily available accessible on the health case entity or review agent's website. **230-RICR-20-30-14.6 (D)(3)(a&b)** 3. Establish and employ a process to transparently incorporate and consider local variations to national standards and criteria identified in this Part including, without limitation, a process to incorporate input from local participating providers. As used in this Part, a process to incorporate and consider local variations to national standards and criteria shall mean a process that: a.Affirmatively and meaningfully solicits, documents and reasonably incorporates input from an objective, independent and diverse pool of local providers, including local participating providers or their representatives; and b. Reasonably considers and documents input and information received from consumer advocacy groups, healthcare professional associations and chronic disease associations, employers, sponsors of health plans or other interested parties concerning clinical criteria.
South Carolina	**MCO Contract Select Health South Carolina 2021** 8.4.2. Adopt practice guidelines in accordance with 42 CFR § 438.236(b). These guidelines must adhere to the following criteria: 8.4.2.1. Are based on valid and reliable clinical evidence or a consensus of

	Physical and Behavioral Health care professionals in the particular field. 8.4.2.2. Consider the needs of the Medicaid Managed Care Members. 8.4.2.3. Are adopted in consultation with contracting physical and Behavioral Health Providers. 8.4.2.4. Are reviewed and updated periodically as appropriate
Tennessee	**T.C.A. §56-6-705(a)(2)(C); (D):** (C) A utilization review agent shall make any current preauthorization requirements and restrictions available on its online provider portal. The utilization review agent shall cite to the standards being used and reference the section of the standards relied upon by the utilization review agent. If the utilization review agent is relying upon proprietary references and documentation in developing the clinical criteria, then the utilization review agent shall provide a citation to the proprietary clinical indications being used. Any nonproprietary supporting references and documentation shall be made available to contracted providers if the utilization review agent develops its own clinical criteria; and (D) If a utilization review agent intends to either implement a new preauthorization requirement or restriction, or amend an existing requirement or restriction, the utilization review agent shall provide contracted health care providers with written notice, or other form of notice under the terms of the contract, of the new or amended requirement or restriction no less than sixty (60) days before the requirement or restriction is implemented and shall ensure that such restriction or requirement has been updated on the utilization review agent's web site.
Texas	**28 Texas Administrative Code (TAC) §19.1705 General Standards of Utilization Review.** (b) Special circumstances. A utilization review determination must be made in a manner that takes special circumstances of the case into account that may require deviation from the norm stated in the screening criteria or relevant guidelines. Special circumstances include, but are not limited to, an individual who has a disability, acute condition, or life-threatening illness. (c) Screening criteria. Each URA must utilize written screening criteria that are evidence-based, scientifically valid, outcome-focused, and that comply with the requirements in Insurance Code §4201.153. The screening criteria must also recognize that if evidence-based medicine is not available for a particular health care service provided, the URA must utilize generally accepted standards of medical practice recognized in the medical community. **Texas Insurance Code (TIC) §4201.153. Screening Criteria and Review Procedures.** (a) A utilization review agent shall use written medically acceptable screening criteria and review procedures that are established and periodically evaluated and updated with appropriate involvement from physicians, including practicing physicians, dentists, and other health care providers. (b) A utilization review determination shall be made in accordance with currently accepted medical or health care practices, taking into account special circumstances of the case that may require deviation from the norm stated in the screening criteria. (c) Screening criteria must be: 1) objective; 2) clinically valid; 3) compatible with established principles of health care; and 4) flexible enough to allow a deviation from the norm when justified on a case-by-case basis. (d) Screening criteria must be used to determine only whether to approve the requested treatment. A denial of requested treatment must be referred to an appropriate physician, dentist, or other health care provider to determine medical necessity.

	Effective 1/1/2020, per TX SB1742 (Section 2.02 Subchapter J, Chapter 843, Section 843.3482: **Prior Authorization Transparency**: Health maintenance organizations and health insurers are required to post preauthorization requirements on their internet website, including screening criteria, any services which require a preauthorization, a description of the preauthorization process, and the effective date of such preauthorization requirements. Additionally, health maintenance organizations and health insurers are required to post on their website statistics regarding preauthorization approval and denial rates for the preceding year. Health maintenance organizations and health insurers must provide at least 60 days' advance written notice to their network before effecting any changes to such preauthorization requirements. For less burdensome changes, such as the removal of a preauthorization requirement, only five days' notice is required.
Utah	**UT SB264 (effective 1/1/20)** Notification of prior authorization requirement modification: An insurer may not modify an existing requirement for authorization unless it notifies network providers in writing or posts the update to its website at least thirty (30) days before the day on which the modification takes effect.
Washington D.C.	**D.C. Managed Care Organization (MCO) Contract- ACDC** C.5.30.5 Medical Necessity Criteria C.5.30.5.2 The Contractor shall ensure that the Medical Necessity Criteria applicable to children age's birth through twenty (20) years of age reflect EPSDT guidelines.

VI. References:

URAC: HUM, Version 7.4 HUM 1 - *Review Criteria Requirements*
NCQA: Version 2022, UM 2- *Clinical Criteria for UM Decisions*

Revision Dates

09/19/2023-Revision to CMS Coverage Hierarchy: Medicare Advantage Medical Policy Development section and Guideline Hierarchy section
05/09/2023-OH Addendum Addition
05/05/2023-Health Equity Statement Added
04/14/2023
03/30/2023
03/24/2023
02/13/2023
01/30/2023
01/27/2023
12/05/2022
11/29/2022
08/22/2022
05/17/2022
12/13/2021
11/30/2021

Approved by: Pamela Dougherty **Date: 09/19/2023**

eviCore healthcare Compliance Officer