Clinical Practice Guideline: **Practice Parameters and Review Criteria**

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Product: **Specialty**

DEVELOPMENT

American Specialty Health - Specialty (ASH) is charged, through its role as a health plan, to ensure that practitioners comply with professionally recognized standards of practice and established diagnostic and treatment planning practices acceptable to ASH's clinical committees. ASH develops practice parameters and review criteria by evaluating professionally recognized standards of practice and existing practice parameters. These practice parameters and review criteria serve as decision-assist tools by which practitioners are evaluated during the credentialing/recredentialing program, clinical services program, and clinical performance program.

ASH defines professionally recognized standards of practice as those based on peer-reviewed, published research and the educational standards accepted by the majority of the profession's accredited educational institutions. Practices and protocols that are incorporated into baseline education, competency training, and certification or licensure testing requirements of the profession's regulators (e.g., national and state boards and/or certifying entities) are also considered contributory to professionally recognized standards of practice. The evaluation of this information will result in the identification and definition of professionally recognized standards of practice in terms of safety, efficiency, clinical rationale, reproducibility, reliability, and an understanding of the rationale behind why practices and procedures are utilized.

These standards produce reasonable, reliable, and expected functional outcomes of the clinical encounter, thus guiding the practitioner and maximizing the clinical benefit to the member. These standards also identify known risks, methods to minimize those risks, and methods to manage adverse outcomes should they occur.

Practice parameters and review criteria have been developed from review of scientific literature and consensus of ASH clinical peer review committees comprised of credentialed practitioners. The purpose of developing practice parameters and review criteria is to provide clinicians and clinical quality evaluators a consistent and reliable method of evaluating diagnostic and therapeutic rationale. These practice parameters and review criteria are evaluated at least annually and may be modified at any time. Current Clinical Practice Guidelines (CPGs) and any pertinent new evidence are reviewed by the Health Services Department clinical research staff on an annual basis. The CPGs then are routed through a defined committee structure for further editing as needed and approval. New

CPGs are constructed by Health Services clinical research staff based on available evidence and then follow the same committee review path. When needed, ASH internal clinicians and subject matter experts and/or external consultants will be called upon to participate in the Evidence Evaluation Committee (EEC) to assist in the review and evaluation of literature pertaining to a new or current CPG. CPGs developed or reviewed by the EEC are also subject to the same committee review path.

CPGs are then reviewed by the Quality Oversight Committee (QOC) on behalf of the Board of Directors (BOD) prior to implementation.

ASH practice parameters and review criteria should:

- Be relevant to clinical practices that ASH members may encounter in a practitioner's office;
- Be rigorous in defense of optimal "best-clinical practice;"[1]
- Consider current optimal best-clinical practice as compared to current common practice; and
- Be consistent with the procedures and processes defined within the credentialing/recredentialing program, clinical services program, and clinical performance program.

Considerations in the development of these practice parameters and review criteria include:

- The practitioner is professionally and ethically responsible for delivering optimally efficient and effective care;
- The practitioner is obligated to the member to establish mutually agreed upon and measurable outcomes of care;
- The practitioner renders services for the sole purpose of substantiating a diagnosis, developing a member-specific treatment plan/program, and/or treating a member's illness or injury;
- The practitioner's purpose of treatment should be to restore the member's functional health status or stabilize a chronic or recurrent condition with an emphasis on self-care and education while promoting non-reliance on ongoing, ineffective treatment;
- ASH is responsible for verifying that safe and effective care is being provided by the treating practitioners;
- ASH is responsible for verifying services that are documented as medically necessary within the limits of the member's applicable benefit plan;

[1] Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

- ASH recognizes that treatment or diagnostic procedures outside of best practices may delay effective care and lead to member harm.

Health care services covered by ASH must be consistent with ASH CPGs and other related policies, are scientifically valid and published in broadly accepted, professional peer-reviewed clinical literature to be safe (defined below), effective (likely to result in expected favorable outcome), and reliable (likely to result in a known outcome each time the procedure is applied).

Evidence-based criteria are defined as those documented clinical concepts, rules, practices, procedures, outcomes, and rationale approved by ASH's clinical committees and QOC, and include the following:

- Supported by valid scientific documented evidence (1) or approved by ASH peer-consensus evidence (2) if valid scientific documented evidence of diagnostic or therapeutic reliability and reproducibility is limited;
- Known to be anatomically and/or physiologically effective and/or based on accepted anatomical and physiological knowledge;
- Safe/low risk (3);
- Based on valid and reliable clinical evidence (4).

(1) Documented evidence:
ASH accepts evidence that has been published in clinical literature and peer-reviewed by an acceptable representative segment of the profession. Documented evidence is demonstrated by independent validity, reliability, and reproducibility, and is derived by accepted scientific methods. Documented evidence may also include valid case series, but emphasis is on high quality systematic reviews/meta-analysis and randomized controlled trials. Anecdotal opinion is not considered valid documented evidence.

(2) Consensus evidence:
Consensus evidence may be accepted as standard of practice by ASH when conclusive, scientifically valid peer-documented evidence is limited, and safety of the practice is established. Consensus evidence is developed through an ASH accepted peer review process that elicits majority consensus regarding a given clinical protocol or practice considering all other clinical characteristics noted above.

(3) Safe/low risk:
A safe clinical practice is one that has a known favorable diagnostic or therapeutic outcome/value; does not place the patient at high risk of direct harm when properly applied; does not result in a potential delay of implementation of a different but established or proven diagnostic or therapeutic procedure; and has a benefit: risk ratio that strongly favors benefit.

ASH defines a procedure as having a favorable benefit: risk ratio if:

- Standards exist to define the appropriate and reproducible application of the procedure; and
- Training of practitioners is adequate to ensure competency; and
- There exists a third-party review system to evaluate the competency of the practitioner; and
- The procedure can be measured and, when compared to current known procedures, is shown to be at least as safe or safer; and
- There are scientifically valid, published data to indicate that the benefit: risk ratio of the procedure favors benefit over risk; or
- There is not scientifically valid, published data indicating that the benefit: risk ratio of the procedure favors risk over benefit.

(4) Clinical evidence:

Clinical evidence is diagnostic and/or therapeutic/intervention evidence determined to be valid and reliable during the clinical assessment and the treatment plan/program. This evidence validates diagnostic methods and determines the efficacy and effectiveness of the treatment plan/program.

A treatment or procedure, a device, or a biological product may be determined by ASH to be experimental, investigational, or unproven if it is determined by a peer consensus review committee that:

1. It is under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the currently accepted professional standard means of treatment or diagnosis; or
2. No credible scientific evidence exists regarding the device or biological product or medical treatment or procedure; or
3. Credible scientific evidence shows that the consensus of opinion among experts regarding the device or biological product or medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the currently accepted professional standard means of treatment or diagnosis; or
4. Consensus of opinion of the ASH EEC and subsequent recommendation of ASH clinical committees regarding the device or biological product or medical treatment or procedure is that current scientific evidence has not shown it to be safe, scientifically plausible, or effective. See the *Medical Necessity Definition (UM 8 – S)* policy for more information.

CLINICAL CRITERIA SUMMARY

Clinical practices delivered by a practitioner or performed in the care of a member must be defined within professionally recognized standards of practice as reflected in ASH practice parameters and review criteria. This perspective recognizes that some health care practitioners deliver health care services that are within their scope of practice, but do not meet the practice parameters defined in this document. ASH recognizes that its practice parameters and review criteria represent a peer-reviewed, evidence-based optimal delivery model of professional practices within the health care disciplines.

CLINICAL DECISION-MAKING

Practice parameters and review criteria for clinical decision-making are designed to determine whether:

- The practitioner's credentials (education, training, license/registration/certification, malpractice coverage and history) are appropriate for their discipline and regulatory requirements;
- The clinical diagnostic and/or treatment practices potentially available to a member meet ASH standards, criteria, and requirements;
- The outcome of a given service occurred because the practitioner was or was not practicing within professionally recognized standards of practice;
- The services provided are medically necessary and/or clinically appropriate, delivered in accordance with professionally recognized standards of practice, and are allowed in the member's contract; and
- A practitioner is willing to improve his/her practices where it was determined that a professional practice was not performed in accordance with ASH criteria.

CLINICAL SERVICES PROGRAM – MEDICAL NECESSITY REVIEW

A key component of ASH benefit administration programs is its Clinical Services Program (CS Program). This is a peer review program that evaluates whether covered services are medically necessary. ASH utilizes licensed, credentialed peer clinical quality evaluators, in compliance with all applicable state and federal regulations to review clinical documentation submitted for medical necessity review based upon the review criteria described in this document and/or other applicable guidelines.

ASH does not set fixed condition-specific treatment frequency or duration limitations. Each case is reviewed by considering pertinent clinical documentation submitted and understanding that similar case presentations should be handled in similar fashion with reasonably consistent results. For a given diagnosis, the effect of variability in general health status (age, gender, past medical history, psychosocial factors, and presence of co-morbid conditions) makes the use of diagnosis-specific treatment tracks inherently untenable.

ASH clinical quality evaluators are available by telephone to respond to practitioners' questions or inquiries regarding the clinical services program or a specific issue related to a case.

The goals of the clinical decision-making processes, which occur at both the practitioner-member interface and the practitioner-ASH interface, are to approve within the member's benefit program, clinical services necessary to restore the member's functional health status, as clinically appropriate, or stabilize a chronic condition for which complete resolution is not possible.

The initial encounter and subsequent clinical encounters between practitioner and member have the purpose of assessing the member's health condition and delivering a treatment care plan/program that addresses the clinical needs of the member based on the results of those assessments. It is the responsibility of the ASH practitioner to document the medical necessity of all treatment/services requested/provided. It is the responsibility of the peer review ASH clinical quality evaluators to evaluate the documentation submitted by the practitioner in accordance with their understanding of professionally recognized standards of practice parameters and review criteria adopted by ASH.

ASH clinical quality evaluators have the responsibility to evaluate submitted treatment/services for medically necessary and covered clinical conditions and/or care. The clinical quality evaluators evaluate the clinical data supplied by the practitioner in order to determine whether the initiation or continuation of care has been documented as necessary. In many cases, the clinical documentation supplied provides sufficient information to establish the need to initiate care, but the member's long-term response to the care cannot be predicted. In these circumstances, the clinical quality evaluator will approve the initiation of the practitioner's proposed treatment plan/program. Approval of continued care may require submission of additional information at various points within the treatment plan/program. In those cases where the member has been approved for a course of treatment and more treatment is requested by the practitioner, the decision to approve additional treatment will be based on documentation submitted to support the necessity and efficacy of further care, including:

- The member has made clinically significant progress under the initial treatment plan/program; clinically significant progress may be documented based on completion of a reliable and valid outcome tool. Actual significance requires correlation with the overall clinical presentation, including updated subjective and objective examination findings;
- Additional clinically significant progress can be reasonably expected by continued treatment;
- The member has not reached maximum therapeutic benefit (MTB) or maximum medical improvement (MMI); and

- There is no indication that immediate care/evaluation is required by other health care professionals.

It is not appropriate to approve ongoing services if the member's condition is no longer improving despite the services being rendered by the treating practitioner. These procedures allow the member to receive appropriate care but take into account the variable responses that a member may have to the clinical intervention.

References

Joint Commission International. (2020). Joint Commission International Accreditation Standards for Hospitals (7th ed.): Joint Commission Resources.