1 **Clinical Practice Guideline: Practice Parameters and Review Criteria**
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3 **Date of Implementation: April 24, 2003**
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5 **Product: Specialty**
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8 **Development**
9 American Specialty Health - Specialty (ASH) is charged, through its role as a health plan,
10 to ensure that practitioners comply with professionally recognized standards of practice
11 and established diagnostic and treatment planning practices acceptable to ASH's clinical
12 committees. ASH develops practice parameters and review criteria by evaluating
13 professionally recognized standards of practice and existing practice parameters. These
14 practice parameters and review criteria serve as decision-assist tools by which
15 practitioners are evaluated during the credentialing, clinical services management,
16 clinical performance management, and recredentialing processes.
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18 ASH defines professionally recognized standards of practice as those based on peer-
19 reviewed, published research data and the educational standards accepted by the majority
20 of the profession's educational institutions. Practices and protocols that are incorporated
21 into baseline education, competency training, and certification or licensure testing
22 requirements of the profession's regulators (e.g., national and state boards and/or
23 certifying entities) are also considered contributory to professionally recognized
24 standards of practice. The evaluation of this information will result in the identification
25 and definition of professionally recognized standards of practice in terms of safety,
26 efficiency, clinical rationale, reproducibility, reliability, and an understanding of the
27 rationale behind why practices and procedures are utilized.
28
29 These standards produce reasonable, reliable, and expected functional outcomes of the
30 clinical encounter, thus guiding the practitioner and maximizing the clinical benefit to the
31 member. These standards also identify known risks, methods to minimize those risks, and
32 methods to manage adverse outcomes should they occur.
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34 Practice parameters and review criteria have been developed from review of scientific
35 literature (see policy Selected List of References - CPG 5 – S), consensus of ASH clinical
36 peer review committees comprised of contracted practitioners, and expert opinion. The
37 purpose of developing practice parameters and review criteria is to provide clinicians and
38 clinical quality evaluators, respectively, a consistent and reliable method of evaluating
39 diagnostic and therapeutic rationale. These practice parameters and review criteria are
40 evaluated at least annually, and may be modified at any time. The Evidence Evaluation
41 Committee (EEC) reviews the published literature related to specific clinical practices,
42 and evaluates the validity and reliability of the clinical practice. Additionally, the

Professional Affairs Healthcare Advisory Committee (PAHAC) may provide input regarding what is taught in the professional schools and/or broadly accepted and commonly practiced. See policy Technology Assessment - QM 4 - S for additional information regarding how EEC, PAHAC, the Clinical Quality Team (CQT), and the Quality Improvement Committee (QIC) - consisting of contracted practitioners - develop clinical policy. Clinical policy is 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, clinical performance management, and clinical services management programs.

Further, the use of these practice parameters should provide acceptable, scientifically valid, professionally ethical, and responsible support for the decisions made in the management of clinical services rendered to members.

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 purpose of treatment is to restore the member's functional health status or stabilize a chronic condition.
- ASH is responsible for supporting clinically safe and effective complementary health care in conjunction with its practitioners;

[1] "Best-clinical practice": An optimal best-clinical practice is a procedure or protocol that is most likely to be utilized by a majority of credentialed peers for the purpose it is being applied, is accepted by the profession's academic institutions to the point of being a component of the core curriculum, is tested to competency by accepted academic institutions and regulatory bodies or agencies, and is the procedure or practice most likely to result in favorable clinical outcomes for the patient/client for which this service may be used.

- ASH is responsible for meeting its members' healthcare needs within the limits of the member's applicable benefit plan;
- ASH has a clinical responsibility to verify as medically necessary only those services that are optimal, efficient, and meet professionally accepted standards of care;
- ASH recognizes that treatment or diagnostic procedures outside of professional standards may delay effective care and lead to member harm.

Health care services covered by ASH must be consistent with ASH Clinical Practice Guidelines 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 is defined as those documented clinical concepts, rules, practices, procedures, outcomes, and rationale approved by ASH's clinical committees and QOC, and includes 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 non-existent;
- Known to be physiologically effective and/or based on accepted physiological knowledge (not experimental/investigational);
- Safe/low risk (3);
- Based on clinical evidence (4).

(1) Documented evidence:
ASH accepts for review 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 studies. Anecdotal opinion is not considered valid documented evidence.

(2) Consensus evidence:
Consensus evidence may be accepted as standard of practice by ASH when scientifically valid peer-documented evidence is non-existent. 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 are no scientifically valid, published data to indicate that the benefit:risk ratio of the procedure favors risk over benefit.

(4) Clinical evidence:

Clinical evidence is diagnostic evidence and/or therapeutic functional outcome 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 of the treatment plan/program.

A treatment or procedure, a device, or a biological product may be determined by ASH to be experimental or investigational 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 policy Medical Necessity Definition - UM 8 – S 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 – Case Evaluation

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 to review clinical documentation submitted for medical necessity review based upon the review criteria described in this document.

Clinical Services Program

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 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 MTB or MMI; and
- There is no indication that immediate care/evaluation is required by other health care professionals.

It is appropriate not 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.

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