

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 practitioners
15 are evaluated during the credentialing/recredentialing program, clinical services program,
16 and clinical performance program.

17
18 ASH defines professionally recognized standards of practice as those based on peer-
19 reviewed, published research and the educational standards accepted by the majority of the
20 profession's accredited educational institutions. Practices and protocols that are
21 incorporated into baseline education, competency training, and certification or licensure
22 testing requirements of the profession's regulators (e.g., national and state boards and/or
23 certifying entities) are also considered contributory to professionally recognized standards
24 of practice. The evaluation of this information will result in the identification and definition
25 of professionally recognized standards of practice in terms of safety, efficiency, clinical
26 rationale, reproducibility, reliability, and an understanding of the rationale behind why
27 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.

33
34 Practice parameters and review criteria have been developed from review of scientific
35 literature and consensus of ASH clinical peer review committees comprised of credentialed
36 practitioners. The purpose of developing practice parameters and review criteria is to
37 provide clinicians and clinical quality evaluators a consistent and reliable method of
38 evaluating diagnostic and therapeutic rationale. These practice parameters and review
39 criteria are evaluated at least annually and may be modified at any time. Current Clinical
40 Practice Guidelines (CPGs) and any pertinent new evidence are reviewed by the Health
41 Services Department clinical research staff on an annual basis. The CPGs then are routed
42 through a defined committee structure for further editing as needed and approval. New

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

7
 8 CPGs are then reviewed by the Quality Oversight Committee (QOC) on behalf of the Board
 9 of Directors (BOD) prior to implementation.

10
 11 ASH practice parameters and review criteria should:

- 12 • Be relevant to clinical practices that ASH members may encounter in a
 13 practitioner’s office
- 14 • Be rigorous in defense of optimal ‘best-clinical practice’¹
- 15 • Consider current optimal best-clinical practice as compared to current common
 16 practice
- 17 • Be consistent with the procedures and processes defined within the
 18 credentialing/recredentialing program, clinical services program, and clinical
 19 performance program

20
 21 Considerations in the development of these practice parameters and review criteria include:

- 22 • The practitioner is professionally and ethically responsible for delivering optimally
 23 efficient and effective care
- 24 • The practitioner is obligated to the member to establish mutually agreed upon and
 25 measurable outcomes of care
- 26 • The practitioner renders services for the sole purpose of substantiating a diagnosis,
 27 developing a member-specific treatment plan/program, and/or treating a member’s
 28 illness or injury
- 29 • The practitioner’s purpose of treatment should be to restore the member’s
 30 functional health status or stabilize a chronic or recurrent condition with an
 31 emphasis on self-care and education while promoting non-reliance on ongoing,
 32 ineffective treatment
- 33 • ASH is responsible for verifying that safe and effective care is being provided by
 34 the treating practitioners
- 35 • ASH is responsible for verifying services that are documented as medically
 36 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).

- 1 • ASH recognizes that treatment or diagnostic procedures outside of best practices
2 may delay effective care and lead to member harm
3

4 Health care services covered by ASH must be consistent with ASH CPGs and other related
5 policies, are scientifically valid and published in broadly accepted, professional peer-
6 reviewed clinical literature to be safe (defined below), effective (likely to result in expected
7 favorable outcome), and reliable (likely to result in a known outcome each time the
8 procedure is applied).
9

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

- 13 • Supported by valid scientific documented evidence (1) or approved by ASH peer-
14 consensus evidence (2) if valid scientific documented evidence of diagnostic or
15 therapeutic reliability and reproducibility is limited
- 16 • Known to be anatomically and/or physiologically effective and/or based on
17 accepted anatomical and physiological knowledge
- 18 • Safe/low risk (3)
- 19 • Based on valid and reliable clinical evidence (4)
20

21 (1) Documented evidence:

22 ASH accepts evidence that has been published in clinical literature and peer-reviewed
23 by an acceptable representative segment of the profession. Documented evidence is
24 demonstrated by independent validity, reliability, and reproducibility, and is derived
25 by accepted scientific methods. Documented evidence may also include valid case
26 series, but emphasis is on high quality systematic reviews/meta-analysis and
27 randomized controlled trials. Anecdotal opinion is not considered valid documented
28 evidence.
29

30 (2) Consensus evidence:

31 Consensus evidence may be accepted as standard of practice by ASH when conclusive,
32 scientifically valid peer-documented evidence is limited, and safety of the practice is
33 established. Consensus evidence is developed through an ASH accepted peer review
34 process that elicits majority consensus regarding a given clinical protocol or practice
35 considering all other clinical characteristics noted above.
36

37 (3) Safe/low risk:

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

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

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

13
14 (4) Clinical evidence:

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

19
20 A treatment or procedure, a device, or a biological product may be determined by ASH to
21 be experimental, investigational, or unproven if it is determined by a peer consensus review
22 committee that:

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

1 **CLINICAL CRITERIA SUMMARY**

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

9
10 **CLINICAL DECISION-MAKING**

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

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

25
26 **CLINICAL SERVICES PROGRAM – MEDICAL NECESSITY REVIEW**

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

33
34 ASH does not set fixed condition-specific treatment frequency or duration limitations.
35 Each case is reviewed by considering pertinent clinical documentation submitted and
36 understanding that similar case presentations should be handled in similar fashion with
37 reasonably consistent results. For a given diagnosis, the effect of variability in general
38 health status (age, gender, past medical history, psychosocial factors, and presence of co-
39 morbid conditions) makes the use of diagnosis-specific treatment tracks inherently
40 untenable.

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

4
 5 The goals of the clinical decision-making processes, which occur at both the practitioner-
 6 member interface and the practitioner-ASH interface, are to approve within the member’s
 7 benefit program, clinical services necessary to restore the member’s functional health
 8 status, as clinically appropriate, or stabilize a chronic condition for which complete
 9 resolution is not possible.

10
 11 The initial encounter and subsequent clinical encounters between practitioner and member
 12 have the purpose of assessing the member’s health condition and delivering a treatment
 13 care plan/program that addresses the clinical needs of the member based on the results of
 14 those assessments. It is the responsibility of the ASH practitioner to document the medical
 15 necessity of all treatment/services requested/provided. It is the responsibility of the peer
 16 review ASH clinical quality evaluators to evaluate the documentation submitted by the
 17 practitioner in accordance with their understanding of professionally recognized standards
 18 of practice parameters and review criteria adopted by ASH.

19
 20 ASH clinical quality evaluators have the responsibility to evaluate submitted
 21 treatment/services for medically necessary and covered clinical conditions and/or care. The
 22 clinical quality evaluators evaluate the clinical data supplied by the practitioner in order to
 23 determine whether the initiation or continuation of care has been documented as necessary.
 24 In many cases, the clinical documentation supplied provides sufficient information to
 25 establish the need to initiate care, but the member’s long-term response to the care cannot
 26 be predicted. In these circumstances, the clinical quality evaluator will approve the
 27 initiation of the practitioner’s proposed treatment plan/program. Approval of continued
 28 care may require submission of additional information at various points within the
 29 treatment plan/program. In those cases where the member has been approved for a course
 30 of treatment and more treatment is requested by the practitioner, the decision to approve
 31 additional treatment will be based on documentation submitted to support the necessity and
 32 efficacy of further care, including:

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

- 1 • There is no indication that immediate care/evaluation is required by other health
2 care professionals.
3

4 It is not appropriate to approve ongoing services if the member’s condition is no longer
5 improving despite the services being rendered by the treating practitioner. These
6 procedures allow the member to receive appropriate care but take into account the variable
7 responses that a member may have to the clinical intervention.
8

9 ***References***

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