

NQTL: Medical Necessity Review	
Classification(s): Inpatient In Network & Out of Network , Outpatient Office In Network & Out of Network, Outpatient All Other In Network & Out of Network and Emergency In Network & Out of Network	
Step 1 – Identify the specific plan or coverage terms or other relevant terms regarding Medical Necessity and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification	
Provide a clear description of the specific NQTL, plan terms, and policies at issue: Wellfleet delegates its non-Pharmacy Utilization Management to Hines & Associates (Hines) for True Choice Plans. Wellfleet and Hines employ the same definition of medical necessity to (M/S) and mental health/substance use disorder (MH/SUD) benefits. Wellfleet applies the definition of “medical necessity” set forth in the governing plan instrument, and in accordance with state law. Notwithstanding the above, Wellfleet standard definition of “medical necessity” is as follows: Wellfleet defines “Medically Necessary/Medical Necessity” as follows: Health care services, supplies and medications provided for the purpose of preventing, evaluating, diagnosing, or treating a Sickness, Injury, condition, disease, or its symptoms, which are all of the following as determined by a Medical Director or Review Organization: • required to diagnose or treat an illness, Injury, disease, or its symptoms. • in accordance with generally accepted standards of medical practice. • clinically appropriate in terms of type, frequency, extent, site, and duration. • not primarily for the convenience of the patient, Physician, or other health care provider. • not more costly than an alternative service(s), medication(s) or supply(ies) that is at least as likely to produce equivalent therapeutic or diagnostic results with the same safety profile as to the prevention, evaluation, diagnosis or treatment of your Sickness, Injury, condition, disease, or its symptoms; and • rendered in the least intensive setting that is appropriate for the delivery of the services, supplies or medications. Where applicable, the Review Organization may compare the cost-effectiveness of alternative services, supplies, medications, or settings when determining least intensive setting.	
Identify the M/S benefits/services for which Medical Necessity is required: All M/S and MH/SUD services, whether in-network or out-of-network must be medically necessary. Services determined by Hines not to be medically necessary would be excluded under the terms of the plan unless otherwise dictated by regulatory requirement or specific plan design.	Identify the MH/SUD benefits/services for which Prior Authorization is required: All M/S and MH/SUD services, whether in-network or out-of-network must be medically necessary. Services determined by Hines not to be medically necessary would be excluded under the terms of the plan unless otherwise dictated by regulatory requirement or specific plan design.
Step 2 – Identify the factors used to determine that Medical Necessity will apply to mental health or substance use disorder benefits and medical or surgical benefits	
Medical/Surgical: 1. Clinical efficacy 2. Safety of services and technologies 3. Appropriateness of the proposed service and technology Factors Considered but rejected (same for M/S and MH/SUD): No other factors were considered and rejected. Weight (same for M/S and MH/SUD): There is no differentiation of weight between the factors. There is no Artificial Intelligence application utilized for the NQTL design.	MH/SUD: 1. Clinical efficacy 2. Safety of services and technologies 3. Appropriateness of the proposed service and technology Factors Considered but rejected (same for M/S and MH/SUD): No other factors were considered and rejected. Weight (same for M/S and MH/SUD): There is no differentiation of weight between the factors. There is no Artificial Intelligence application utilized for the NQTL design.

Step 3 – Identify the evidentiary standards used for the factors identified in Step 2, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply Medical Necessity to mental health or substance use disorder benefits and medical or surgical benefits.

- Analyses should explain whether any factors were given more weight than others and the reason(s) for doing so, including an evaluation of any specific data used in the determination.
- To the extent the plan or issuer defines any of the factors, evidentiary standards, strategies, or processes in a quantitative manner, it must include the precise definitions used and any supporting sources.

Medical/Surgical:

1. Factor 1: Clinical Efficacy
SOURCE: MCG Guidelines
MCG Care Guidelines are created by clinical editors that analyze and classify peer reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence based medicine.
SOURCE: US FDA
EVIDENTIARY STANDARDS:
Peer-reviewed published medical literature
Evidence-based consensus statements
Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies
Technology assessments and structured evidence reviews
Clinical training, experience, and judgment of clinical reviewers

2. Factor 2: Safety of services and technologies**SOURCE:** MCG Guidelines
MCG Care Guidelines are created by clinical editors that analyze and classify peer reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence based medicine
EVIDENTIARY STANDARDS:
Peer-reviewed published medical literature
Evidence-based consensus statements
Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies
Technology assessments and structured evidence reviews clinical training, experience, and judgment of HMAC clinical reviewers

3. Factor 3: Appropriateness of the proposed service and technology
SOURCE: MCG Guidelines
MCG Care Guidelines are created by clinical editors that analyze and classify peer reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence based medicine.
EVIDENTIARY STANDARDS:
Peer-reviewed published medical literature
Evidence-based consensus statements
Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies

MH/SUD:

1. Clinical Efficacy
SOURCE: MCG Guidelines
MCG Care Guidelines are created by clinical editors that analyze and classify peer reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence based medicine.
SOURCE: LOCUS/CALOCUS Guidelines & ASAM Criteria
Hines uses the criteria published by requests. Deerfield Behavioral Health, Inc.'s LOCUS and CALOCUS guidelines were developed by members of the American Association of Community Psychiatrists (AACP). Both are a level of care assessment tool used by behavioral health managers and clinicians throughout the country to support accurate level of care recommendations. These tools assess the current clinical needs of the individual to establish the intensity of services found along the continuum of care.
EVIDENTIARY STANDARDS:
Peer-reviewed published medical literature
Evidence-based consensus statements
Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies
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Peer-reviewed published medical literature
Evidence-based consensus statements

Technology assessments and structured evidence reviews Clinical training, experience, and judgment of clinical reviewers	Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies Technology assessments and structured evidence reviews Clinical training, experience, and judgment of HMAC clinical reviewers 3. Factor 3: Appropriateness of the proposed service and technology SOURCE: MCG Guidelines MCG Care Guidelines are created by clinical editors that analyze and classify peer reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence based medicine. SOURCE: LOCUS/CALOCUS Guidelines & ASAM Criteria Hines uses the criteria published by requests or state mandates. Deerfield Behavioral Health, Inc.'s LOCUS and CALOCUS guidelines were developed by members of the American Association of Community Psychiatrists (AACP). Both are a level of care assessment tool used by behavioral health managers and clinicians throughout the country to support accurate level of care recommendations. These tools assess the current clinical needs of the individual to establish the intensity of services found along the continuum of care EVIDENTIARY STANDARDS: Peer-reviewed published medical literature Evidence-based consensus statements Evidence-based guidelines from nationally recognized professional healthcare organizations and public health agencies Technology assessments and structured evidence reviews Clinical training, experience, and judgment of clinical reviewers
Step 4 – Provide the comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification. <i>The analyses, as documented, should explain whether there is any variation in the application of a guideline or standard used by the plan or issuer between MH/SUD and medical/surgical benefits and, if so, describe the process and factors used for establishing that variation.</i> ☐ <i>If the application of the NQTL turns on specific decisions in administration of the benefits, the plan or issuer should identify the nature of the decisions, the decision maker(s), the timing of the decisions, and the qualifications of the decision maker(s).</i> ☐ <i>If the plan's or issuer's analyses rely upon any experts, the analyses, as documented, should include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluations in setting recommendations regarding both MH/SUD and medical/surgical benefits.</i>	
All information below is applicable to M/S classifications. Hines utilization review team is composed of physicians and nurses and includes specialists from both medical and behavioral health disciplines. Internal subject matter experts include, but are not limited to orthopedists, neurologists, neurosurgeons, OBGYNs, oncologists, primary care physicians, internist, surgeons, urologists, pulmonologists, cardiologists, psychologists, and psychiatrists. The utilization review team reviews up to date literature with the latest version to determine medical necessity pertaining to the various medical and behavioral health services,	All information below is applicable to MH/SUD classifications. Hines utilization review team is composed of physicians and nurses and includes specialists from both medical and behavioral health disciplines. Internal subject matter experts include, but are not limited to orthopedists, neurologists, neurosurgeons, OBGYNs, oncologists, primary care physicians, internist, surgeons, urologists, pulmonologists, cardiologists, psychologists, and psychiatrists. and the utilization review team reviews up to date literature with the latest version to determine medical necessity pertaining to the various medical and behavioral health

therapies, procedures, devices, technologies, and pharmaceuticals to be used for utilization management purposes based on the cpt code level. This includes materials that address M/S services determined to be experimental and investigational.

Hines may incorporate without limitation and as applicable, criteria relating to U.S. Food and Drug Administration-approved labeling, the standard medical reference compendia including MCG Guidelines for both MS and MHSUD, ASAM Criteria for SUD.

Hines utilization review team reviews clinical research and guidelines for new clinical procedures and technologies to determine whether these services have demonstrated clinical efficacy or are still deemed experimental/investigational.

The company's routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) process is used to evaluate consistency for clinical decision making across reviewers making medical necessity determinations on clinical review literature. IRR reviews are conducted according to accreditation standards.

Hines Policy II-A3-4.1 Certification Requiring Additional Review Medical Necessity Adverse Determination illustrates when a determination not to certify a prospective or concurrent confinement or procedure for reason of lacking medical necessity must be made by a Hines Physician Advisor (PA). The determination not to certify for reason of medical necessity should not be made without the physician reviewer attempting a peer- to-peer discussion with the attending/treating physician of record, although an adverse determination can be made without discussion with the attending physician. A decision must be reached and that decision must be verbally relayed to the attending MD within the time guidelines set forth by the Department of Labor, URAC standards or applicable state regulations. The attending physician is to be notified of the denial, the rationale for the determination, and of the appeals process. The formal denial process will be followed as defined in the Policy on Notification of Denials.

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Step 4(b): Identify and define the factors and processes that are used to monitor and evaluate the application of Prior Authorization for M/S benefits:

Authorizations

UR Service Level	Inpt	Inpt	Inpt	TOTAL INPT REVIEWS	UR Service Level	Outpt	Outpt	TOTAL OUTPT REVIEWS
Auth Type	Precert	Concurrent	Retro		Auth Type	Precert	Retro	
MED SURG					MED SURG			
Approvals	38	101	92	231	Approvals	565	144	709
Denials	3	15	13	31	Denials	43	72	115
MedSurg % Denied	7%	13%	12%	12%	MedSurg % Denied	1%	33%	14%
MH					MH			
Approvals	27	85	33	145	Approvals	11	3	14
Denials	0	40	2	42	Denials	1	1	2
MH % Denied	0%	32%	6%	22%	MH % Denied	8%	25%	13%
SUD					SUD			
Approvals	6	8	2	16	Approvals	0	0	0
Denials	3	1	1	5	Denials	0	0	0
SUD % Denied	33%	11%	33%	24%	SUD % Denied	0%	0%	0%

APPEALS

UR Service Level	Inpt	Inpt	Inpt	TOTAL INPT REVIEWS	UR Service Level	Outpt	Outpt	TOTAL OUTPT REVIEWS
Auth Type	Precert	Concurrent	Retro		Auth Type	Precert	Retro	
MedSurg					MedSurg			
Denials Upheld	0	0	1	1	Denials Upheld	0	14	14
Denials Overturned	0	0	1	1	Denials Overturned	0	12	12
MedSurg % Upheld	0%	0%	50%	50%	MedSurg % Upheld	0%	46%	46%
MH					MH			
Denials Upheld	0	0	4	4	Denials Upheld	0	0	0
Denials Overturned	0	0	2	2	Denials Overturned	0	0	0
MH % Upheld	0%	0%	33%	33%	MH % Upheld	0%	0%	0%
SUD					SUD			
Denials Upheld	0	0	2	2	Denials Upheld	0	0	0
Denials Overturned	0	0	0	0	Denials Overturned	0	0	0
SUD % Upheld	0%	0%	0%	0%	SUD % Upheld	0%	0%	0%

Wellfleet monitors the Wellfleet-Hines book of business (BoB) utilization management data. Utilization management is the process that evaluates the efficiency and appropriateness of the treatment, procedures, or service requested. Hines utilization management clinicians and physicians use the medical necessity criteria from MCG Guidelines, and ASAM Criteria or state specific requirements to make their determination.

The 2024 Wellfleet –Hines BoB

The number of utilization review decisions across the Wellfleet- Hines book of business data reflects comparable average denial rates but with significant variation in the number of reviews for MHSUD based upon Medical Necessity across all inpatient and outpatient benefit classifications for utilization management programs including prior authorization, concurrent review, and retrospective review with medical necessity denials for M/S services higher than medical necessity denials of MH/SUD services. Appeals data includes the same time period relating to the utilization management data metrics.

Step 5 – Provide the specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results that indicate that the plan or coverage is or is not in compliance with this section.

This discussion should include citations to any specific evidence considered and any results of analyses indicating that the plan or coverage is or is not in compliance with MHPAEA

As written:

A review of Wellfleet- Hines's factors, evidentiary standards, sources, and as written and in operation processes reveals the comparable application of Medical Necessity to M/S and MH/SUD services within the applicable benefit classification. Hines Medical Necessity process is consistent between M/S and MH/SUD. Hines applies comparable evidence- based guidelines to define established standards of effective care in both M/S and MH/SUD benefits. Compliance is further demonstrated through Hines' uniform definition of Medical Necessity for M/S and MH/SUD benefits. Consistency in policy development, process, and application demonstrates that the medical necessity is applied comparably, and no more stringently, to MH/SUD services than to M/S services.

Wellfleet has not identified any additional discrepancies in operational policies between MH/SUD and M/S benefits where the discrepancies present a comparability or stringency problem within the context of the NQTL requirement. Hines conducts routine (occurring no less frequently than annually) Inter-Rater Reliability (IRR) testing which is used to evaluate consistency of clinical decision-making across reviewers and to identify any potential revisions to coverage policies that may be warranted. Corrective action is initiated if a score falls below 85% and if the results are below 90% the Medical Director will evaluate the scores and decide whether to convene a review process with the Medical Directors/Physician Reviewers. Of note, the company's most recent MH/SUD IRR exercise did not reveal a need to revise its policies governing reviews of MH/SUD benefits.

Thus, Wellfleet has determined that Medical Necessity Review is applied for MH/SUD benefits in a manner that is comparable to and no more stringent than that of M/S services, both as written and in operation, based on the information presented above that describes in detail the evidentiary standards, processes, strategies, and factors used to impose Medical Necessity Reviews.