State of Connecticut

GENERAL ASSEMBLY



MEDICAL INEFFICIENCY COMMITTEE LEGISLATIVE OFFICE BLDG. SUITE 2000 STATE CAPITOL HARTFORD, CONNECTICUT 06106 240-0490

May 2, 2011

Governor Dannel Malloy Hartford, CT 06102

Re: Medical Inefficiency Committee 2011 Report

Dear Governor Malloy,

Attached you will find the second of three reports authorized for the General Assembly under P.A. 09-03 section 81(b) and P.A. 09-07 section 107(b). The first report was issued in February of 2010. The legislation was established to advise the Department of Social Services on the amended definition of "medically necessity" utilized in the State Medicaid program. The statute also requires the committee to provide feedback to the General Assembly on the impact of the amended definition.

Over the past year the committee and its subcommittees have held several meetings along with invited guests from the Department of Social Services, Department of Mental Health and Addiction Services, the Healthcare Advocate, and the general public. We believe we have reached consensus on a definition, which is contained in the report, and are planning to focus on training and implementation in the last year of our assignment.

If you have any questions, please let us know.

Sincerely,

J. Kevin Kinsella, Ph.D. Co-Chair Alicia Woodsby, MSW Co-Chair

Cc: Senator Harp Representative Walker Senator Musto Representative Tercyak Senator Gerratana Representative Ritter Representative Donovan Senator Williams Representative Cafero Senator McKinney

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MEDICAL INEFFICIENCY COMMITTEE LEGISLATIVE OFFICE BLDG. SUITE 2000 STATE CAPITOL HARTFORD, CONNECTICUT 06106 240-0490

2010 - 2011 Membership

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Introduction:

The state budget passed in 2009 charged the Department of Social Services with amending the definition of "medically necessary" services utilized in the administration of Medicaid to reflect savings in the current biennial budget by reducing inefficiencies in the administration of the program, while not reducing the quality of care provided to Medicaid beneficiaries. The statute also established a Medical Inefficiency Committee to advise the Department of Social Services on the amended definition and implementation, and to provide feedback to the department and the General Assembly on the impact of the amended definition. The Department of Social Services (the Department) attended all of the meetings of the Medical Inefficiency Committee (the Committee) and was an integral part of the process of developing the new definition of medically necessity proposed by the Committee.

In 2010, the Committee's proposed new definition of medical necessity passed in House Bill 5545 and became law in Section 22 of Public Act 10-3. The definition was drafted by both DSS and the Committee, with both stakeholders having input into, and compromising on, the definition. Their objective was not only to make sure that medical inefficiencies were reduced, but also to improve the level of care or at least ensure that the level of care was maintained.

Section 22 of Public Act 10-3

Statutory Language and Summary from the Office of Legislative Research

Sec. 22. (NEW) (*Effective from passage*) (a) For purposes of the administration of the medical assistance programs by the Department of Social Services, "medically necessary" and "medical necessity" mean those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors;

(2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease;

(3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers;

(4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and

(5) based on an assessment of the individual and his or her medical condition. (b) Clinical policies, medical policies, clinical criteria or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested health service shall be used solely as guidelines and shall not be the basis for a final determination of medical necessity. (c) Upon denial of a request for authorization of

services based on medical necessity, the individual shall be notified that, upon request, the Department of Social Services shall provide a copy of the specific guideline or criteria, or portion thereof, other than the medical necessity definition provided in subsection (a) of this section, that was considered by the department or an entity acting on behalf of the department in making the determination of medical necessity. (d) The Department of Social Services shall amend or repeal any definitions in the regulations of Connecticut state agencies that are inconsistent with the definition of medical necessity provided in subsection (a) of this section, including the definitions of medical appropriateness and medically appropriate, that are used in administering the department's medical assistance program. The commissioner shall implement policies and procedures to carry out the provisions of this section while in the process of adopting such policies and procedures in regulation form, provided notice of intent to adopt the regulations is published in the Connecticut Law Journal not later than twenty days after implementation. Such policies and procedures shall be valid until the time the final regulations are adopted.

Office of Legislative Research Summary for PA 3

§§ 22 & 27 — MEDICAL NECESSITY

New Definition

The bill statutorily establishes a definition of "medically necessary" and "medical necessity" in DSS' medical assistance programs. The definition is:

Those health services required to prevent, identify, diagnose, treat, rehabilitate, or ameliorate an individual's medical condition, including mental illness, or its effect, in order to attain or maintain the individual's achievable health and independent functioning, provided such services are (1) consistent with generally accepted standards of medical practice that are defined as standards that are based on (a) credible scientific peer-reviewed medical literature that is generally recognized by the relevant medical community, (b) recommendations of a physician-specialty society, (c) the view of physicians practicing in relevant clinical areas, and (d) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, sites, extent, and duration and considered effective for the individual's illness, injury, or disease; (3) not primarily for the convenience of the individual, the individual's health care provider, or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury, or disease; and (5) based on an assessment of the individual and his or her medical condition.

DSS currently uses two medical necessity and medically necessary definitions in its medical assistance programs, neither of which is in statute. The SAGA medical assistance program regulations use the following definition:

Health services required to prevent, identify, diagnose, treat, rehabilitate, or ameliorate a health problem or its effects, or to maintain health and functioning, provided such services are:

1. consistent with generally accepted standards of medical practice;

2. clinically appropriate in terms of type, frequency, timing, site, and duration;

3. demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists; and

4. efficient in regard to the avoidance of waste and refraining from provision of services that, on the basis of the best available scientific evidence, are not likely to produce benefit.

DSS uses the following definition of medical necessity (also "medically necessary") in the Medicaid fee-forservice, HUSKY, and Charter Oak Health Plan:

Health care provided to correct or diminish the adverse effects of a medical condition or mental illness; to assist an individual in attaining or maintaining an optimal level of health; to diagnose a condition or prevent a medical condition from occurring.

Use of Clinical Guidelines

Under the bill, clinical and medical policies, clinical criteria, or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested health services may be used solely as a guideline and cannot be the basis for a final medical necessity determination.

When Service Denied Based on Medical Necessity

The bill provides that if a request for authorization of services is denied based on medical necessity, the individual must be notified that, upon request, DSS will provide a copy of the specific guideline or criteria, or portion thereof, other than the medical necessity definition that DSS or any other entity acting for it considered when making a medical necessity determination.

Repealing Existing Regulations and Implementing Change While in Process of Adopting New Regulations

The bill permits DSS to amend or repeal any regulatory definition of medical necessity, including the definitions of medical appropriateness and medically appropriate, used in administering the "medical assistance program," (presumably Medicaid, which is sometimes referred to as medical assistance in statute).

The bill requires the commissioner to implement policies and procedures to carry out the definition change while in the process of adopting them in regulation. He must publish notice of intent to adopt the regulations in the *Connecticut Law Journal* within 20 days of implementation. These policies and procedures are valid until the final regulations are adopted.

The bill eliminates language rendered obsolete by the above provisions.

Medical Inefficiency Committee

The bill increases from three to four, the number of members the Governor must appoint to the Medical Inefficiency Committee. It also specifies that the House Speaker and Senate President must jointly select the committee chairs from among its members. By law, the committee must (1) advise DSS on the amended definition of "medically necessary" and "medical necessity" and its implementation (see Section 22) and 2) to provide feedback to DSS and the legislature on its impact.

Interpretation of subsection (a)(1) Generally-accepted standards of medical practice:

Concerns over the Department's Interpretation. Shortly after the implementation of the new definition of Medical Necessity, concerns arose that the Department was interpreting the definition in a way that restricts access to medically necessary services by requiring *all* elements of Sec. 22 (a)(1) of PA 10-3 to be met before a service is considered medically necessary. This is not consistent with the intent of the Committee or the statute, which does not mandate, explicitly or implicitly that a particular service must satisfy all of these factors to be medically necessary. The statute clearly states that medical necessity standards must merely be "based on" the factors enumerated in (a)(1). In fact it would be rare for any treatment or service to satisfy all of these elements.

Healthcare Advocate's Objection. On January 4, 2011, the state's Healthcare Advocate, Kevin Lembo, submitted a letter to the Commissioner of the Department of Social Services requesting confirmation that the Department will interpret the medical necessity definition as it has been construed since passage, and indicating that the Healthcare Advocate's office will pursue legislation to fix the Department's incorrect interpretation if it does not receive a commitment to return to the intended interpretation of section 22 of Public Act 10-3 (see Appendix A).

Commissioner's Response. In the Department's response on February 17, 2011, the Commissioner stated that the Healthcare Advocate's concern that the Department will interpret medical necessity in a manner that needlessly restricts access by requiring that all elements of subsection (a)(1) be met before a service is to be considered medically necessary is "not entirely consistent with the Department's interpretation of subsection (a)(1) of the definition" (see Appendix B). The Commissioner further notes that, "the Department's interpretation of this clause is that all of its elements be collectively used to weigh whether the first part of the medical necessity definition is met. Data or information to support only one of the criteria in subsection (a)(1) does not necessarily support a finding of medical necessity. This is especially true if stronger, more relevant or more recent evidence exists under one or more criteria. Accordingly, *the use of "and" in the construction of subsection* (a)(1) was intentional and is consistent with the Department's application."

The Commissioner's response is not entirely consistent with the response of the DSS Medical Director on November 23, 2010, when he described the definition as a hierarchy. He stated that if there are generally accepted standards of care in a particular arena, then that should be considered first when making the call about what is medically necessary. If there are not generally accepted standards of care then the specialists would be the next to be consulted, then the local experts and then any relevant factors should be considered when making these decisions. This is the way he would interpret the definition as the DSS Medical Director, although, *"the definition is not constructed in this way and the committee could consider modifying the definition to conform to this hierarchy"* (see MIC Meeting Minutes 11.23.10). The DSS Medical Director further stated that his understanding is that we have four different ways of finding generally accepted medical practice, and that it was possible to determine medical necessity if only one element was met (see MIC Meeting Minutes 2.22.11).

Committee Recommendation: Based upon the Department's commitment, subsequent to the Commissioner's February 17, 2011 letter, to disseminate the new Provider Bulletin agreed upon in Appendix F., the Committee does not recommend a technical change to subsection (a)(1) at this time.

MCO Reporting Requirements:

The Committee recommended changes to the guidance that the Department provided to the MCOs in August 2010 on required reporting on the impact of the new definition of medical necessity. The Committee requested clarification that clinical criteria or guidelines cannot be cited as the basis for a denial. The

Department accepted the Committee's recommendations and reissued the revised guidance to the MCOs on February 23, 2011 (see Appendix C).

Notice of Action Documents:

The Department worked collaboratively with the Committee on several implementation documents related to the new medical necessity definition, including the Notice of Action (NOA) template that was issued to the Managed Care Organizations (see Appendix D). The Department accepted several changes offered by Committee members during a subcommittee meeting on 12/20/2010. In addition, the Department decided to create separate NOAs for denials based on <u>coverage</u> versus those based on <u>medical necessity</u>. In general, the Department requires the MCOs to adopt their template verbatim, allowing for just the insertion of identifiers and logos (see Appendix D).

Cumulative Data for Denials and Partial Denials:

The Department shared four charts with the Committee showing denials, partial denials, approvals, and prior authorizations per 1,000 member months (see Charts below).

Across all of the plans, there were 43,847 prior authorization requests and 43,660 full approvals in the first quarter of 2010; 25,071 requests and 22,880 approvals in the second quarter; 24,869 requests and 22,747 approvals in the third quarter.

The Department noted that Aetna changed its prior authorization policy after the first quarter, which explains the drop in numbers. Aetna was said to have done this because its denial rates for prior authorization were so low to begin with that it was financially unwise to continue requiring so many. The Committee noted the very low rate of denials. Some skepticism was expressed related to whether or not the numbers presented by the MCOs were accurate as to how partial and full denials were being counted.

The Department indicated that there will likely be changes in how data will be recorded as the state moves from MCOs to the new ASO system.









Case Examples:

As requested by the Committee, the Department agreed to provide case examples of denials to the Committee for joint review. The two service categories initially requested include inpatient hospital and outpatient surgery, and occupational and physical therapy. The Department provided multiple case examples of claims that were denied based on lack of medical necessity (see Appendix E).

The Committee noted constant references to the clinical guidelines, which should not be a basis for a denial. The Committee suggested that in the next round of examples going forward, the Department could clarify what part of the definition of medical necessity was used in making the denial. The Committee requested behavioral health examples for the second review of case examples.

Provider Bulletins:

An initial Provider Bulletin was issued in October 2010 by the Department entitled "Post-payment Review of Behavioral Health Services" (see DSS Provider Bulletin 2010-61). The Bulletin indicated the intent of the Department of Social Services (DSS) and the Department of Mental Health and Addiction Services (DMHAS) to perform joint post-payment medical necessity reviews of behavioral health services provided to Medicaid and Medicaid for Low Income Adults (LIA) clients since July 1, 2010. The Bulletin included the new definition of medical necessity, and noted that reviews may include, but will not be limited to, the medical necessity of services provided in accordance with the new statutory medical necessity definition established pursuant to Public Act 09-3 for Medicaid and other medical assistance programs administered by the Department of Social Services.

Serious concerns were expressed by providers and advocates over the connection between the audits and the new medical necessity definition, and, especially, the context in which the new definition was initially introduced to the provider community. The concern was that the Department was communicating that there is now a tighter definition of medical necessity, and that they will be auditing the providers based on this new tighter definition. Some providers perceived that the Department was asserting that they must do the audits because of the changes implemented with the new definition, when there should not have been significant change occurring with the new definition.

A hospital representative noted in a Committee meeting on November 23, 2010 that "in talking to different hospitals that are going through audits, there is definitely a sense that the new definition is more restrictive" (see MIC Meeting Minutes 11.23.10).

Committee Recommendation: The Committee requested that the Department issue a general Provider Bulletin to introduce the new definition of medical necessity that is separate from any audit or post-payment review process. The Department drafted such a Provider Bulletin with input from the Committee (see Appendix F). The Committee strongly recommends that the Bulletin be disseminated to all providers in the Connecticut Medical Assistance Program.

Provider Education:

As a result of the post-payment reviews for behavioral health services and the Provider Bulletin referenced above, several providers reached out to the Committee to express concerns about the new definition of medical necessity being more restrictive than the former Medicaid and SAGA definitions. In response to these concerns, the Committee invited community behavioral health and substance abuse providers to its meeting on November 23, 2010 to gain a better understanding of the confusion and concerns related to the new definition.

The providers noted that DSS has not given providers training on the new definition, documentation requirements and the audit process. It was mentioned that audits will be conducted to this new definition. Many organizations were audited for the first time in 20 years by the Department. One provider felt that there was consensus that, during the auditing process, there was a lot of subjectivity to the interpretation of clinical documents. A request was made for information clarifying what one documents in clinical records so as to be prepared for an audit. The frustration lies in that the provider organization asked DSS for the audit guidelines and they would not provide it (see MIC Meeting Minutes 11.23.10). This same provider was referred to the Medicaid contract, which has many layers of state and federal regulation from which providers had to determine what was the audit tool. The provider noted that they have gone to great lengths to make sure that they are in compliance, but training for both the auditors and the providers would make the process more clear.

Some providers were concerned about the lack of official notice of the new definition. It had not been published or posted in locations where it should be.

Providers were also concerned about the retroactive application of the new definition in audits. A concern over the weight given to evidence published in peer-reviewed medical literature was described as an issue for many in the substance abuse treatment field, as it short-changes peer-reviewed interventions not documented in the medical literature. Peer review does not have that kind of support behind it, so this may lead to a significant reorientation within the field. One provider expressed that DMHAS has been recognized nationally for their cutting-edge approach of using peers in the process of treatment planning, recovery and intervention, and since this definition is driven by a medically oriented model, this type of peer treatment may be lost.

The Department responded that many of the people conducting the audits are new at this process and have a great deal to learn. Auditors have also had questions about how to approach the process and for guidance as well. The Department agreed to take the comments back and see what they can do to address the situation (see MIC Meeting Minutes 11.23.10).

Providers described a potential conflict in the interpretation of the extent of the treatment. Interpretation varies around levels of medication, types and number of groups the patient may need to join, if the patient needs individual and/or family therapy, and the level of observation that the patient needs. The duration of a patient's stay was also a concern. If a facility is unable to discharge a patient because a less restrictive level of care is not available or that alternative does not adequately maintain a patient's safety, then a continued higher level of care is warranted. Putting a patient in the least restrictive level of care may not be the best option for a patient.

Additionally, the substance abuse providers have been working with DMHAS for 15 to 20 years on creating a model of care that has, in many respects, been altered by Medicaid LIA, as LIA is a very different model. They see it as very physician-driven model that downplays the role of the peer; going as far as to diminish the role of professionals who are not physicians. One provider described the difficulty in serving individuals, families and communities when providers are required to provide treatment plans which are geared towards meeting Medicaid guidelines. Licensing regulations state that the language should be written with children and families. It is difficult to serve both the auditors for medical necessity and parent and children who are dealing with a variety of different issues.

One of the major concerns expressed by the providers was the fact that the individual context and flexibility allowed under SAGA with peer-oriented and recovery services differs from the medical model required by Medicaid. There also appeared to be auditing process issues, and Medicaid model issues. There was a clear need for guidance and training in regard to the definition of medical necessity. There were important issues in regard to what was provided under SAGA and what is provided under Medicaid.

Furthermore, a main concern regarding the new definition was the standard that a service be "not more costly than an alternative service or sequence of services at least as likely to produce *equivalent therapeutic or diagnostic results* as to the diagnosis or treatment of the individual's illness, injury or disease." The Committee noted that under the former Medicaid definition, medical necessity and medical appropriateness were the two standards that were used for determinations. Under medical appropriateness the standard was "least costly of multiple *equally-effective alternative* treatment or diagnostic modalities." Therefore, there is no significant difference between the new definition and the former Medicaid definition, and in fact, a less restrictive change from the former SAGA definition in which the standard was the least costly of "*similarly effective*" alternatives.

Committee Recommendation: The Committee concluded that although the providers had important concerns, they are not necessarily issues with the medical necessity definition. Providers expressed significant concerns around what really appeared to be more about Medicaid regulation, moving from the SAGA model to a Medicaid model, and auditing issues. However, it is clear that it would be beneficial for providers to know how auditors are interpreting the new definition of medical necessity and applying it.

The CT Community Providers Association (CCPA) and CT Nonprofits offered to host such an event in collaboration with the Department and the Committee. The importance of involvement by both the DSS medical assistance and quality assurance units was stressed by the providers. Medical assistance can describe the intent, but quality assurance conducts the provider audits. There needs to be consistency in their interpretations of the definition.

The Committee recommends that the training be held in late April or early May, and include the provider associations, the Committee, and the Department. The training should cover the meaning of the definition, how providers can ensure compliance, and how Medicaid auditors will test to determine if the definition has been met. Written materials should be developed and distributed, so that others not able to attend have consistent information. A video of the training should be made available.

APPENDIX A.



January 4, 2011

Michael P. Starkowski Commissioner Department of Social Services 25 Sigourney St. Hartford, CT 06106

Re: Public Act 10-3, Section 22, Medical Necessity

Dear Commissioner Starkowski:

I write because it has come to my attention that the Medicaid Director at the Department of Social Services is attempting to re-interpret Section 22 of Public Act 10-3, in a more restrictive and inappropriate manner than the language of the Act or its intent allows. As you know, the Medical Inefficiency Committee spent considerable time drafting a definition of medical necessity that is both consistent with current commercial definitions of medical necessity, yet sensitive to the needs of Medicaid recipients, fulfilling the statutory mandate that the amended definition not reduce the quality of care provided to Medicaid beneficiaries.

I oppose a restrictive reading that attempts to restrict access to medically necessary services by requiring that <u>all</u> elements of subsection (a)(1) must be met before a service is to be considered medically necessary. Such a reading is plainly unworkable and creates an absurd result. It is possible under the Department's reading that there could be internal contradictions between subdivisions of subsection (a)(1), For instance, it is possible for there not to be specialty society recommendations, while credible scientific evidence published in the peer-reviewed medical literature. It also is possible for other relevant factors of clinical judgment to precede credible scientific evidence published in peer reviewed journals. Moreover, it would be rare, if not impossible, for any treatment to satisfy all of the elements, which were never intended as a set of requirements.

When I testified before the committee last year, he noted that it was important that "any other relevant factors" remain in the definition of medical necessity for the precise reason that there are times that procedures or services do not rise to the level of a generally accepted standard. I gave the following example to the committee:

In fact, it might be experimental or investigational, but the patient's circumstances preclude any other option. For instance -- patient has developed malignant tumors in her liver ten years after having her right breast and five lymph nodes removed. During treatment for her original cancer, the patient had numerous radiation treatments and chemotherapy trials that left her lungs weakened. She and her doctor made a decision to remove the liver tumors by radioactive ablation therapy, a non-invasive procedure considered "experimental and investigational" by the insurer. The insurer denied the claim on that basis, and [OHA] argued that the carrier had to consider any relevant factors, including the evidence of success of the procedure in many cases with similarly situated individuals, and that in the particular case, where the patient had no other alternative-traditional surgery was not an option because of her lung damage--the procedure was medically necessary. The carrier upheld its denial and approved the ablation treatment. On an expedited external appeal, we won the case and got this patient's care covered

It was widely agreed by the committee that such an example met the definition of medical necessity then under consideration and subsequently adopted by the committee. It is also my understanding that the Department at the time of its adoption fully understood and agreed with the Committee that any of the elements in (a)(1) could be the basis for a finding of medical necessity.

In none of these examples I cited is it appropriate to conclude that a service is not medically necessary merely because all elements are not satisfied. Your medical director has remarked publicly that it would be nearly impossible to meet all the elements of subsection (a)(1). Clearly, the legislature did not intend to put the kinds of restrictions on medically necessary care that the Department is now considering through an untenable reading of the statute.

Please confirm that you will not erect this barrier to state medical assistance, and that you will interpret the medical necessity definition as it has been construed since passage. This office will pursue legislation to fix the Department's incorrect interpretation if I do not receive a commitment from you to return to the intended interpretation of section 22 of Public Act 10-3.

Thank you for your prompt attention to this matter.

Very truly yours,

Kevin Lembo, MPA Healthcare Advocate

cc (by e-mail only): Alicia Woodsby, Co-Chair, Medical Inefficiency Committee Kevin Kinsella, Co-Chair, Medical Inefficiency Committee Mark Schaefer, Director Medical Care Administration, DSS Robert Zavoski, Medical Director, DSS



Commissioner

MICHAEL P. STARKOWSKI

STATE OF CONNECTICUT DEPARTMENT OF SOCIAL SERVICES

OFFICE OF THE COMMISSIONER

TELEPHONE (860) 424-5053 TED/TTY 1-800-842-4524 FAX (860) 424-5057 EMAIL commis.dss://ct.gov

February 17, 2011

Victoria Veltri, Acting Healtheare Advocate Office of the Healtheare Advocate State of Connecticut P.O. Box 1543 Hartford, CT 06144

Dear Ms Veltri,

I am writing to respond to the January 4, 2011 letter sent to me by former Healthcare Advocate Kevin Lembo regarding the legislation establishing the new medical necessity definition for the Department of Social Services health care programs, Public Act 10-3, Section 22. Mr. Lembo expressed concerns with the Department's interpretation of the first section of the new definition. In particular, he stated that the Department is reinterpreting the definition in an overly restrictive and inappropriate manner, inconsistent with the language or intent of the Act. I appreciate and share the Office of the Healthcare Advocate's commitment to maintaining access to medically necessary services for Medicaid and other medical assistance program clients. I therefore wish to allay any concerns about the Department's interpretation of the new definition.

Mr. Lembo's concern centers on the first section of the new definition, which provides that medically necessary services must be:

(1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors;

Mr. Lembo's major concern is that the Department will interpret medical necessity in a manner that needlessly restricts access to services by requiring that "all elements of subsection $(a)(1) \dots$ be met before a service is to be considered medically necessary." That characterization is not entirely consistent with the Department's interpretation of subsection(a)(1) of the definition. The Department's interpretation of this clause is that all of its elements be collectively used to weigh whether the first part of the medical necessity definition is met. Data or information to support only one of the criteria in subsection (a)(1) does not necessarily support a finding of medical necessity. This is especially true if stronger, more relevant or more recent evidence exists under one or more of the other criteria. Accordingly, the use of "and" in the construction of subsection (a)(1) was intentional and is consistent with the Department's application.

25 SIGOURNEY STREET • HARTFORD, CONNECTICUT 06106-5033 An Equal Opportunity / Affirmative Action Employer Printed on Recycled ar Recovered Paper www.ct.gov/dss Victoria Veltri, Acting Healthcare Advocate February 17, 2011 Page 2

We fully agree with Mr. Lembo's assertion that not all requested services either undergo scientific review published in peer-reviewed periodicals or are reviewed and recommended by appropriate specialty societies. Furthermore, in the Department's experience, research findings or specialty society recommendations frequently conflict, at least to some degree, on the safety or efficacy of some treatments or services. Medical necessity determinations must therefore weigh sometimes conflicting information while taking into account relevant factors unique to the specific client.

It is important to recognize that the Department's implementation of the new definition is undergoing considerable public scrutiny. The Medical Inefficiency Committee has requested and subsequently received significant amounts of data and other information from the Department and the Medicaid managed care plans, which the Committee has used to review and critique the Department's implementation. We believe this is exceptional degree of reporting and transparency has and will continue to demonstrate that the Department's interpretation of medical necessity is not overly restrictive and is not a barrier to necessary state medical assistance.

I hope this addresses your concerns about the Department's interpretation of the new definition of medical necessity. If you have further concerns about this matter, please feel free to contact the Department's medical Director, Dr. Robert Zavoski directly at 860-424-5583 or <u>Robert ravoski@ict.gov</u>. Again, thank you for your continued advocacy on behalf of medical assistance clients.

Sincerely yours

Michael P. Starkowski, Commissioner

Ce: Kevin Lembo Mark Schaefer Robert Zavoski Brenda Parrella Patricia McCoory Kevin Kinsella Alicia Woodsby

APPENDIX C.

Department of Social Services Medical Care Administration

Memorandum

Date:February 23, 2011To:Medicaid Medical DirectorsFrom:Robert Zavoski, MD, MPH

Re: Reporting Related to the Required Application of the New Medical Necessity Definition

As outlined in the August 16, 2010 guidance entitled "New Medical Necessity Definition", the Department of Social Services is required to report data on the impact of the new definition of medical necessity to the both the Medicaid Care Management Oversight Council and the Medical Inefficiency Committee of the General Assembly. The previous guidance defined standards for consistent reporting by the Medicaid managed care plans. The previous guidance also noted that reporting requirements would likely need to be adapted further as experience with the new definition grew and based on feedback from the Medical Inefficiency Committee.

Medically necessary services are defined in Section 22 of Public Act 10-3 as those health services required to "prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning." To be medical necessary, health services must meet five criteria: 1) generally accepted standards of care/other evidence; 2) appropriate intensity/frequency/duration/setting; 3) not a convenience; 4) not more costly than a therapeutically equivalent alternative; and 5) based on an individualized assessment of the member's needs. These five criteria serve as the basis for reporting of coverage decisions.

Although more than one criterion will apply to some denials and should be reflected on the MCO's notices of action, for simplicity and clarity of reporting, the MCO should report only the primary or most compelling basis for the denial.

The statute further requires that "Clinical policies, medical policies, clinical criteria or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested health service shall be used solely as guidelines and shall not be the basis for a final determination of medical necessity." The requirement that the legal definition of medical necessity, and not clinical guidelines, criteria or other expert opinions, must serve as the ultimate basis for determination of medical necessity is consistent with the Department's long-standing contract requirements and other policy and guidance to the MCOs.

In addition, the statute further provides that "Upon denial of a request for authorization of services based on medical necessity, the individual shall be notified that, upon request, the Department of Social Services shall provide a copy of the specific guideline or criteria, or portion thereof, other than the medical necessity definition provided in subsection (a) of this section, that was considered by the department or an entity acting on behalf of the department in making the determination of medical necessity." This requirement applies to all MCOs administering the Medicaid program under contract with DSS; all notices of action must advise that a copy of any criteria used in making the denial decision is available upon request.

Cc: Mark Schaefer Trish McCooey Brenda Parrella Richard Spencer Kathy Brennan Yulia Chillington Annie Jacob Erica Garcia

APPENDIX D.

2 15 11 CT DSS NOA1 – MN Denial

NOTICE OF ACTION FOR DENIED SERVICES OR GOODS [MEDICAL NECESSITY]

DATE:_____

TO:	[Member's Name/ID Number] [Address]
FROM :	[Name of Contact Person] [MCO NAME] [Address] [Telephone Number]

Your Provider's Request for Authorization for: [Service(s) or Good(s) requested]

has been [*denied* or *partially denied*] because it is not medically necessary. [*The service or good requested*] (*one or more reasons may be checked; delete any reasons that are not checked*) is not medically necessary because:

	It does not 1	neet ge	enerally	accepted	standards	of	care
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Explain:

It is not the right type, level, amount or length for you

[Identify alternative service or good or intensity or frequency or duration]:

Explain: _____

It will not be provided in the right health care setting

[Identify alternative level or setting]:

Explain: _____

It is really meant to make things easier for you or your provider

Explain: ______

It costs more than a different service that will be as effective for you

Explain: _____

□ It is not based upon your specific medical condition

Explain:

• We did not get enough information from your provider to show that the service(s) or good(s) is [are] medically necessary for you. Your provider must give us information that shows that the service(s) or good(s) is [are] medically necessary: Explain:

MEDICALLY NECESSARY

Your HUSKY A plan, [MCO NAME], must provide you with all covered services that are "medically necessary."

Medically necessary means medical, dental and behavior services needed to:

- Keep you as healthy as possible
- Improve your health
- Identify or treat an illness or condition
- Help you get better after an injury
- Help you function as best as you can on your own

Medically necessary services must:

- Meet generally accepted standards of medical care;
- Be the right type, level, amount or length for you;
- Be provided in the right health care setting;
- Not be provided as a convenience for you or for your provider;
- Cost no more than a different service that will produce the same results; and
- Be based on your specific medical condition.

The full legal definition of Medically Necessary/Medical Necessity is in Connecticut General Statutes Section 17b-259b.

For a copy of the definition, follow this link: <u>http://www.cga.ct.gov/2011/pub/chap319v.htm#Sec17b-259b.htm</u>, or call [*MCO NAME MCO Member Services*] and ask them to send you a copy.

You have the right to review your file and all documents [MCO NAME] relied upon in making its decision.

APPEAL RIGHTS

YOU HAVE A RIGHT TO APPEAL THIS DECISION BY FILING AN APPEAL FORM WITH THE DEPARTMENT OF SOCIAL SERVICES (DSS).

There are two steps in the appeal and hearing process. They are explained on the enclosed <u>"What You Should Know"</u> information sheet. Sending the attached form to DSS will start both steps. The request form must be postmarked within sixty (60) days of the date this notice was mailed by [MCO NAME]. If not, you will lose your right to challenge this decision.

EXPEDITED APPEALS AND HEARINGS

You can ask for an expedited (quicker) appeal and hearing if the regular decision deadlines put your life or health at serious risk or could seriously affect your ability to function. You must show us that an expedited appeal/hearing is needed or your provider must

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tell us why an expedited appeal is needed. If an expedited appeal is needed, [MCO NAME] will decide your appeal no more than three business days after DSS receives your request. If your hearing is expedited, DSS will schedule a hearing in 3 days.

If you have any questions, you may contact: [SIGNED AND PRINTED NAME/TITLE] at [*Telephone number*] or [*MCO NAME*] Member Services at [*TOLL FREE NUMER*].

If you believe that you have been treated unfairly because of race, color, sex, age, physical or mental disability, religious creed, national origin, sexual orientation, ancestry, language barriers or political beliefs, you have a right to appeal to the Commissioner of Social Services, the Commission on Human Rights and Opportunities, or the U.S. Department of Health and Human Services.

APPENDIX E.

Case Examples

Case 1

- o Date Received: 04/16/2010
 - 13yo female with sensoral-neurol hearing loss in one ear and cochlear implant in the other. Request for continued speech therapy. Clinical information received did not provide enough information that member was making progress toward any goals. Requested latest speech evaluation from member's school and requesting therapist refused stating that the information would not indicate member requires additional services.
- o Date Denied: 04/19/2010
 - Request denied for lack of information documented continued need for services.

Case 2

- o Date Received: 05/07/2010
 - 5yo male diagnosed with developmental disorders including delayed speech. Request for continued speech therapy. Member is Husky B, Income Band 1. Referred to Husky B + Physical Program and Aetna Better Health Case Management Department.
- o Date Denied: 05/11/2010
 - Request denied and referral made.

Case 3

- o Date Received: 05/13/2010
 - 15 yo female diagnosed with morbid obesity and muscle weakness. Past medical history has no documentation of muscle weakness. Request for continued Physical Therapy. Clinical obtained stated that member has partially met her goals, and that her past participation has been inconsistent. Member enrolled in Fit 5 program.
- o Date Denied: 05/14/2010
 - Denied due to inconsistent attendance, and no clear documentation of muscular weakness, it appears that member is attending physical therapy for morbid obesity and does not meet medical necessity criteria for physical therapy.

Case 4

- o Date Received: 05/19/2010
 - 4yo male diagnosed with developmental disorder, and lack of coordination requesting Occupational Therapy, with low muscle tone and fine motor/handwriting skills, which affects his functioning in the home and school settings. Attends preschool where he receives schoolbased speech therapy (2x/week), occupational therapy (2x/week), and physical therapy (lx/week).
 - He started school at the end of November 2009. This therapist conducted standardized testing to assess Stephen's fine motor skills, in addition parent report was provided and clinical observations were completed. Able to undress himself-donning clothes is difficult, clothing fasteners are difficult- able to use fork & spoon functionally at meals.
- o Date Denied: 05/21/2010
 - Denied as duplication of services.

Case 5

- Date Received: 08/13/2010
 - 5yo male diagnosed with muscle weakness and muscle spasm requesting continuing Occupational Therapy. Member currently receiving these services in school.
- Date Denied: 08/26/2010
 - Denied as a duplication of services.

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- o Date Received: 06/16/2010
 - 37yo female requesting perineoplasty independently of physician. Per clinical information received: surgery is not being ordered by MD since it is not medically necessary.
 - Member is insisting on sending in request to insurance even though it is a cosmetic procedure for perineoplasty due to member feeling her vaginal opening is too large and does not like appearance. Also in notes member has cancelled and re-scheduled procedure several times.
- o Date Denied: 06/16/2010
 - Denied as cosmetic in nature.

Case 7

- o Date Received: 06/17/2010
 - 15yo female diagnosed with hypothyroidism and closed fracture of septum. Requesting rhinoplasty and otoplasty. Member has history of fracture of nose, and is displeased with appearance of both her nose and ears. No history of pain or infection described.

o Date Denied: 6/18/2010

Denied as cosmetic in nature.

Case 8

- o Date Received: Original Receipt of Request: 07/08/2009
- o Date of Re-request: 05/03/2010
 - 15 yo female diagnosed with macromastia and shoulder pain requesting bilateral breast reduction. Per information obtained, no conservative treatment tried like pain medications and/or special bras. In addition, no evidence that member has stopped growing due to age of 15 years.
- o Original denial performed 07/14/2009
- Same clinical presented again in 2010, denial upheld
- Date Denied: 07/02/2010
 - Denied as inappropriate due to age. Additional information submitted to Medical Director after peer to peer meeting. Per Medical Director, no new information obtained, denial upheld.

Case 9

- o Date Received: 06/18/2010
 - 27yo female diagnosed with hypertrophy of breast requesting bilateral breast reduction surgery. The amount of breast tissue to be removed did not meet medical necessity criteria, amount too low per criteria.
- o Date Denied: 06/21/2010
 - Denied based on Medical Necessity criteria.

Case 10

- o Date Received: 06/02/2010
 - 47yo female diagnosed with venous insufficiency requesting stab phlebectomy for varicose veins. Per clinical information received member did not meet medical necessity criteria as the saphenofemoral vein was not incompetent.
- o Date Denied: 06/03/2010
 - Denied, did not meet medical necessity criteria.

Case 1

Pertinent Member Information

- 29 year old Husky A female with diagnosis of hypertrophy of breast (enlarged breasts)
- Member requested bilateral breast reduction (both sides)
- Member weighs 175 lbs and is 5'3, garment size 38D
- Request denied as the mass of the breast does not appear excessive as noted from photos. There is no shoulder grooving, no rash or infection. The surgeon plans to remove 200 grams of tissue per breast.

• The criteria used to make this decision was InterQual (Hand, Plastic and Reconstruction and does not meet 110 symptoms. (See Case 1 Criteria file.)

Case 2

Pertinent Member Information

- 6 year old Husky A male with diagnosis of developmental speech disorder with mild articulation deficit characterized by frontal protrusion of the tongue when saying "s", "z" and "s" blends (difficulty pronouncing words with "s" and "z")
- Members conversation illustrates excellent understanding of auditory comprehension and verbal expression for his age level.
- Request denied as there is no medical diagnosis given that shows the need for speech therapy

Case 3

Pertinent Member Information

- 6 year old Husky A male with diagnosis of stuttering.
- Member's evaluation showed mild stuttering and repetition of some short words and syllables. There are no other speech problems noted and he presents as age appropriate for his speech.
- Member evaluated by local public schools system and found to be ineligible for speech therapy services.
- Request denied due to no medical diagnosis to support the need for speech therapy.

Case 4

Pertinent Member Information

- 4 year old Husky B female with diagnosis of articulation/phonological disorder (annunciation of words/vocal sounds)
- Member's evaluation showed she fell into the 8th percentile which is one and a half standard deviations below the mean.
- Member's hearing and vision are normal.
- Member has a moderate delay in acquisition of speech sounds.
- Request denied due to no medical diagnosis to support the need for speech therapy.

Case 5

Pertinent Member Information

- 4 year old Husky A male with diagnosis of mixed receptive expressive language disorder
- Member has delayed development of speech and language and also has difficulty speaking in the class room and social settings.
- Request denied due to no medical diagnosis to support the need for speech therapy.

Case 7

Pertinent Member Information

- 5 month old Husky A male with past medical history of pneumonia, asthma and eczema who presents with a diagnosis of muscle spasm of the back of his head, right upper to mid chest and right back muscles.
- Requested chiropractic services.
- Request denied as the clinical notes did not show the medical need for chiropractic services.
- The infant may be seen by a physical therapist.

Case 8

Pertinent Member Information

- 31 year old Husky A female diagnosis of morbid obesity. She has a past medical history of bipolar psychiatric disorder, high blood pressure and back pain.
- Her past surgeries include gall bladder removal, multiple back surgeries and eye surgery.
- Requested gastric bypass surgery
- Request denied as the psychiatric evaluation did not state the member is a good candidate for surgery.
- Criteria used to make decision is the General Surgery-Bariatric Surgery InterQual criteria. Indication 133 not met. (See Case 8 criteria file.)

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Case 1

Request for hysterectomy

Member information: 37 year old with menorrhagia (excessive or frequent menstruation).

Information reviewed; gynecology surgeon's office notes, ultrasound report, prior surgery report from 2005, follow up calls to the surgeon's office re: prior treatment.

How the decision was reached: the physician reviewer consulted "Milliman Care Guidelines S-650, Abdominal Hysterectomy" specific to the member's conditions of "abnormal uterine bleeding."

Hysterectomy is indicated for abnormal uterine bleeding with all of the following:

- Endometrial sampling or hysteroscopy performed, and no specific etiology (e.g. endometrial hyperplasia) identified.
- Hormonal treatment as appropriate
- Failure of conservative surgical management with curettage, hysteroscopy, or endometrial ablation (18) (19)
- No desire for future fertility

There were no results of endometrial samplings (surgical pathology report of results of endometrial biopsy), the member did not want to try hormone replacement therapy, and there was no notation of conservative treatment. Three of the four required criteria were not met, therefore the procedure was denied.

Case 2

Request for Gastric bypass surgery Member information: 37 year old female.

Appears there was confusion regarding the procedure requested; removal of gastric band vs gastric bypass surgery,, and the clinical information supplied. Denial letter sent 7/8/10, with subsequent approval 8/11/10.

7/8 request reviewed by Dr. He will approve outpt surgery for removal of lap band at Danbury Hospital. Susan at mdo advised and will fax approval to her. Faxed 7/9

8/10 received request for Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Rouxen-Y gastroenterostomy (roux limb 150 cm or less) (43644) and Laparoscopy, surgical, gastric restrictive device and subcutaneous port components (43774).

Gastric bypass has been denied as member had not had medical, pulmonary, nutritional or psych consultations. Member had lap band placed over 2 years ago and no new clinicals obtained. Office will be obtaining new records.

New clinicals received from medical, pulmonary, psych and nutritional consults on 8/10. Criteria reviewed: ORG:S-513 (ISC) Milliman guidelines 14th Ed. Appears to meet Miliman guidelines with new medical information.

8/11 approved gastric bypass based on recent clinical information.

Case 3

Request for physical therapy- 24 weekly visits were requested. 20 were approved and 4 were denied.

6 year old boy with gross motor delay, trunk and leg weakness.

Information reviewed: clinical information from ongoing PT visits; weekly visits were approved in May 2009, October 2009 and March 2010.

How the decision was reached: Physician reviewer looked o Milliman Care Guidelines ACG-A-0364 Spine Soft Tissue Dysfunctional Rehabilitation. Based upon the review, it was determined that the therapy was warranted. Our guidelines are to approve 20 visits and have ongoing communication with the provider to determine if additional visits are needed and will be beneficial.

Case 4

Request for frenoplasty (clipping the frenulum under the tongue, treatment of "tongue tied")

12 year old boy, unable to stick tongue out past lips, some difficulty with speech.

Information reviewed: Surgeon's office note

How the decision was reached; in order to establish medical necessity, the physician reviewer consulted "Milliman care Guidelines ACG A-0186 (AC) Lingual Frenoloplasty and Frenotomy (Frenectomy and Frenulectomy)."

Lingual frenuloplasty or frenotomy (frenectomy or frenulectomy) may be indicated for Speech articulation difficulties if due to ankyloglossia (tongue-tie), as determined by liscensed speech language pathologist.

There was no speech language pathologist assessment of speech articulation difficulties, so the procedure was denied.

Case 5

Request for Panniculectomy (removal of hanging fat and skin over the abdomen which can occur after significant weight loss).

Member information: 37 year old female, 160 lb weight loss after bariatric (gastric bypass) surgery.

Information reviewed; surgeon's office note, followup phone call to the office, photographs of the member's arms.

How the decision was reached: Request from the surgeon is for "body contoring" which is primarily cosmetic. In order to establish medical necessity, the physician consulted "milliman Care Guidelines ACG A-0498 (AC) Panniculectomy."

Panniculectomy is most commonly performed after massive weight loss associated with bariatric surgery. Panniculectomy is usually performed for chronic intertrigo, other skin infection, ulceration, or mechanical irritation that has not responded to medical treatment.

The progress note did not mention chronic intertrigo. A follow up call was made to the office to specifically ask this question. Reviewer was informed that the member had used an over the counter medicine but had not seen her physician for intertrigo. There was no evidence of medical condition (chronic intertrigo) so the procedure was denied.

Case 6

Request for Jaw Surgery

Reconstruction of manibular rami and/or body, sagittal split; with internal rigid fixation (21196) and econstruction midface, LeFort I; single piece, segment movement in any direction (21141).

Member information: 19 year old female with jaw deformities (mandibular hyperplasia and manibular hypoplasia). Her physician notes that she said, "I don't like how my gums show too much and my two front teeth look like buck-teeth."

How the decision was reached: surgeon notes were reviewed in order to understand the specific deformity and how it affected the member. Of note, "19 year old female with significant dental findings include excessive gingival display on maxilla, Bilateral class I molar and Class I canine on right and Class II canine on left." Photographs take at age 17 were sent for review. The reviewing MD requested current photographs. Photographs were not received, and a 14-day extension was granted on 8/4. Photographs were again requested, but were not sent. The reviewing physician did not have updated information upon which to make a decision, so the procedure was denied.



TO: All Providers

RE: Definition of Medical Necessity

The purpose of this bulletin is to inform providers of the definition of medical necessity enacted through a 2010 legislative change. Conn. Gen. Stat. Section 17b-259b (2011)

The definition went into effect on April 14, 2010 and applies to all of the Department's Medical Assistance programs. In the near future, the Department will promulgate regulations to delete references to the former definition and incorporate the new definition. The regulations will also remove all references to "medically appropriate" and "medical appropriateness," which have been superseded by the new definition.

The new definition provides as follows:

(a) For purposes of the administration of the medical assistance programs by the Department of Social Services, "medically necessary" and "medical necessity" mean those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are:

(1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on:

- (A) credible scientific evidence published in peerreviewed medical literature that is generally recognized by the relevant medical community,
- (B) recommendations of a physician-specialty society,
- (C) the views of physicians practicing in relevant clinical areas, and
- (D) any other relevant factors;

(2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease;

(3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers;

(4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and

(5) based on an assessment of the individual and his or her medical condition.

The first requirement of the new definition, (a)(1), provides that in order to be medically necessary, a good or service must be consistent with generally accepted standards of medical practice as demonstrated by: evidence in the medical literature, other professional recommendations or other factors. It is not necessary or possible that <u>all</u> of the factors or criteria contained in requirement (a)(1)(A) through (D) be satisfied for every service. For example, many treatments have not been subjected to peer-reviewed clinical trials or studies but may still be necessary to patient care per one or more of the other criteria.

The fact that a treatment meets one or more of the criteria does not mean that it necessarily meets the definition. One of the other criteria may indicate lack of medical necessity and may be weighted more heavily if it reflects stronger, more relevant or more recent evidence. Again, to the extent relevant evidence is available, each of the criteria that comprise (a)(1) should be weighted to determine if this requirement is satisfied.

In contrast to the four subparts of (a)(1) which call for the balancing described in the preceding paragraph, all five requirements ((1) through (5)) of the new definition must be met for a requested service to be deemed to be medically necessary.

Furthermore, if requested services are denied, the Department (or its agent) when issuing the denial

Questions? Need assistance? Call the HP Provider Assistance Center Mon.-Fri. 8:00 a.m. - 5:00 p.m. In-state toll free 800-842-8440 or Out-of-state or in the local Farmington, CT area 860-269-2028 Or write to HP, PO Box 2991, Hartford CT 06104 / Program information at <u>www.ctdssmap.com</u>



must, upon request, make available to the patient copies of any clinical policies, criteria or guidelines used to assist in the evaluation for the service requested for medical necessity. Such criteria, policies or guidelines may only assist in making the determination of medical necessity; only the definition (above) may be the basis for the determination of medical necessity.

Posting Instructions: Policy transmittals can be downloaded from the web site at <u>www.ctdssmap.com</u>

Distribution: This policy transmittal is being distributed to providers of the Connecticut Medical Assistance Program Provider Manual by HP Enterprise Services.

Responsible Unit: DSS, Medical Care Administration, Patricia McCooey, Staff Attorney, Medical Policy at (860) 424-4873.

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