Connecticut Department of Social Services

Making a Difference

Medical Inefficiency: Perspective of the Department

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March 3, 2010

Medical Necessity in a Broader Context

- The Problem of Medical Inefficiency
- The Medical Review Process
- The Value of Medical Necessity Review
- The Department's Proposed Definition
- The Committee's Proposed Definition
- Concluding Remarks

The Problem of Medical Inefficiency

US Health Care Spending

- During the worst economic downturn in 80 years:
  - US healthcare spending rose an estimated 5.7 percent – to a total of $2.5 trillion in 2009.
  - The percentage of the GDP spent on healthcare saw the largest one-year increase since 1960 (16.2% to 17.3%).
  - In human terms, this represents $7,800 per year for every man, woman and child in the US.
- Medicaid spending grew even faster (9.9%) in 2009
- Spending projected to nearly double to $4.5 trillion in 2019, accounting for almost one-fifth of our GDP

US Health Care Spending

- Despite spending more per capita than any other nation, we are ranked:
  - 39th for infant mortality
  - 43rd for adult female mortality
  - 42nd for adult male mortality
  - 36th for life expectancy

US Health Care Spending

- Drivers of health costs:
  - Technology
  - Defensive medical practices
  - Lifestyle
  - Excessive end-of-life care, proliferation of specialty services, emergency department overutilization
  - Demand induced by supply and marketing
  - Profit

Excessive Health Spending

- Dartmouth Atlas: Per capita Medicare spending differs by as much as a factor of 2 between different U.S. cities when price is removed as a factor, with no difference in health or outcomes.
- Congressional Budget Office estimates that 5% of the nation's gross domestic product — $700 billion per year — is spent on tests and procedures that do not actually improve health outcomes

Unnecessary Health Spending

- According to a 2006 study, during a routine medical checkup, 43% of patients undergo an unnecessary medical test. During 4,600 preventive exams without specific symptoms to trigger testing
  - 37% of checkups included a urinalysis
  - 9% of checkups included an electrocardiogram
  - 8% of checkups included an X-ray
  - 43% of checkups included at least one of these three tests

Medicine on the Defensive

- Defensive medicine is a well-documented response to malpractice litigation and may lead to excessive diagnostics
- Estimates for the cost of defensive medicine
  - more than $100 billion annually in the US
  - up to 12% of all health care expenditures, according to one 2005 national study
- A study conducted by the Massachusetts Medical Society in 2008 found that 83% of physicians reported practicing defensive medicine

Risk of Unnecessary Care

- Examples of overtreatment that may harm patients:
  - Imaging, opiates, surgery for low back pain rather than conservative measures
  - Unnecessary psychiatric stays, especially for children
  - Unnecessary CT scans – lifetime risk for children's exposure
  - Unnecessary anti-psychotic drugs for behavior control - metabolic syndrome, diabetes, life-threatening side effects, sudden cardiac death in geriatric patients

Profit and Marketing – Health Care

- Entrepreneurial behavior is a cost driver in modern health care:
  - Physicians "encouraged" to use products such as replacement joints or implantable cardiac devices for which they receive "research" support
  - Physiatrists on retainer for durable medical equipment (DME) companies to "help" with wheelchair fitting, etc.
  - DME stores that specialize in "getting reimbursement from Medicare"
  - Specialty surgical centers that market "improved" outcomes
  - Hospital or other institutions who advertise their services to referring providers worldwide

Profit and Marketing In Health Care Pharmaceuticals

- Domestic pharmaceutical sales totaled $189 billion in 2008, including:
  - $20.5 billion spent on promotions and marketing
  - Includes $4.7 billion on direct to consumer (DTC) advertising
- One study estimates pharmaceutical manufacturers distributed free samples with a retail value of $18.4 billion in 2005

Are the "Free" Samples Truly Free?

- Marketing and promotional efforts aimed at physicians and other prescribers may have educational value, keeping them abreast of latest drug therapies, and improving their ability to treat patients
- These efforts may also lead physicians to prescribe more expensive brand-name medications rather than proven effective, lower cost alternatives
- Side effects are typically not as well understood compared to the drugs that are well established, particularly with regard to the effect of long term use

Pharmaceutical Litigation

- Recent wave of safety recalls and lawsuits related to marketing, suppression of safety concerns, and other practices, including:
  - Promotion of off-label uses of drugs, including atypical antipsychotics, including a $1.4 billion settlement for marketing unapproved uses in federal insurance programs. This is the largest individual criminal fine in U.S. history.
  - Connecticut recovered more than $25 million in a settlement over promotion of off label uses of Zyprexa in children among others - Zyprexa has never been approved by the FDA for any use in children.
- Recent study shows children covered by Medicaid are given antipsychotic medications at a rate four times higher than children whose parents have private insurance.

Behavioral Health Medications Medicaid Utilization

- Atypical antipsychotics account for nearly 50% of all costs for BH medications for children in HUSKY
- Anti-psychotics were
  - 3 of top 5 prescribed drugs for children in Medicaid
  - 3 of top 3 prescribed drugs for DCF involved children
- Most of this prescribing is for uses other than psychosis, mania, and autism related behavior

Medical Necessity in a Broader Context

- Regardless of the outcome of national health care reform efforts, there will be:
  - Increased focus on safety, efficiency, quality and effectiveness
  - Comparative Effectiveness Research (CER) - *Measuring effectiveness and safety so we know what works and what doesn't work*

Summary

- Unnecessary and inappropriate care is a problem
- Profit drives better healthcare, but also drives unnecessary and inappropriate care
- Unnecessary and inappropriate care harms many patients

The Medical Review Process

Which Services Require Medical Necessity Review?

- Inpatient Hospital and Nursing Home
- Pharmacy (non-PDL and some brand)
- Selected surgeries
- Medical equipment and supplies (such as customized wheelchairs, higher cost equipment)
- Home health – skilled nursing and aide
- Outpatient rehabilitation services (PT, Speech, and OT)
- Dental services including permanent crowns, full dentures, replacements for fillings less than one year old
- High cost community behavioral health

Medical Review Process

- Information provided by clinician to MCO
- Initial review against medical necessity criteria
- If questionable, referred for physician review
- Physician may confer with provider (peer review)
- MCO physician reviewer considers request in light of medical necessity definition
- Authorization denied if not medically necessary

Client Protections

- Notice of action if service denied

If client appeals:

- Internal appeal process at MCO by physician not involved in original review and administrative hearing

If client appeals:

- Court appeal is available

The Value of Medical Necessity Review

Value of Medical Necessity Review
Psychiatric Inpatient Length of Stay

- Accepted wisdom was that long term psychiatric hospitalization, even as long as 2 years for adolescents, was the preferred course of treatment
- These lengthy stays were common at Connecticut's state of the art inpatient psychiatric facilities
- Managed care prompted a change in the model toward short term evaluation and crisis stabilization
- Managed care supported the development of community-based alternatives

Value of Medical Necessity Review
Dental – Full vs. Partial Denture

- Partial denture requested for patient whose remaining teeth were severely diseased.
  - Authorization was denied, partial denture would fail, needless suffering for patient and there would be a cost of unnecessary procedures
  - Authorized full denture alternative
  - Patient acknowledged diseased state of remaining teeth and had requested full denture alternative initially
  - Note a partial denture is reimbursed at $622.44 while a full denture is reimbursed at $277.16

Value of Medical Necessity Review
Dental – Primary Tooth Pulpotomy

- Dentist intentionally drills into pulp in child's primary tooth
  - The tooth receives a pulpotomy & stainless steel crown
  - Financial incentive to provide pulpotomy & crown
  - Prior authorization now requires that dentist provide the CTDHP with X-rays, before the pulpotomy is performed and after when the procedure has not been prior authorized
  - Nerve damage due to advanced decay is readily distinguishable from intentional drilling on x-ray
  - The practice of intentional drilling has essentially been eliminated

Finding a Balance

- risk and cost of unnecessary and inappropriate care

with

- risk and burden of medical necessity review

Criticisms of the Department's Proposed Definition

Response to Criticisms

We will examine each of the cases and concerns raised by clients, providers and advocates over the past few months to determine the effect of the proposed definitions on client's health and safety, provider's ability to practice quality health care.

Department's Proposed Definition of Medical Necessity

- Implemented in SAGA Program in 2004:
- medically necessary means those 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:
  - a) consistent with generally accepted standards of medical practice;
  - b) clinically appropriate in terms of type, frequency, timing, site and duration;
  - c) demonstrated through scientific evidence to be safe and effective and the least costly among similarly effective alternatives, where adequate scientific evidence exists; and
  - d) 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.*

*See Department's proposed alternative

Letter to Legislators from numerous advocacy and consumer groups
May 21, 2009

Examples of potential harm:

- A 32 year old with a traumatic brain injury requiring a wheelchair lift to access second floor of his home
- A 10 year old with trauma and limp denied 10 further hours of physical therapy which would cure the limp
- A 41 year old with schizophrenia poorly controlled on generic clozapine; well controlled on brand Clozaril
- A 52 year old with stage 2 breast cancer requiring adjuvant therapy with 30% rate of success

32 year old with a traumatic brain injury requiring equipment to access second floor of his home

- Individuals with TBI who are at risk of institutionalization, qualify for home and community based waiver services
- Under the waiver, assistive technology, medical equipment and home modifications are available, subject to demonstration of need and within the limits of the waiver cost cap
- Such requests are currently subject to individual review and consideration based on need
- The proposed definition would not further restrict access to these services, whether provided under the state plan or a waiver

10 year old with trauma and limp denied 10 further hours of physical therapy which would cure the limp

- Given this scenario:
  - We agree that curing the limp would be consistent with generally accepted standards of medical practice
  - 10 weeks of therapy to achieve a cure would appear to be clinically appropriate
- This request would be approved

10 year old with trauma and limp denied 10 further hours of physical therapy which would cure the limp

- However, the more likely scenario is:
  - PT recommends another 2 – 4 visits over 6 – 8 weeks and the MD obliges with order without having reassessed the patient,
  - Review of the progress notes from the previous 20 visits shows minimal improvement
- Is authorization of the 10 extra visits appropriate?
- Should the department defer to the judgment of the prescribing physician?

41 year old with schizophrenia, controlled with Clozaril, not with generic clozapine

- It is not consistent with generally accepted standards of medical practice to migrate a patient to a medication that reduces but does not eliminate the symptoms
- Although clozapine is the least costly of the two options, it is not similarly effective because it does not provide adequate symptom control

52 year old w/ stage 2 breast cancer requiring adjuvant therapy with 30% rate of success

- The proposed definition has not resulted in denials of authorization in situations where the likelihood of success is less than 50%
- Moreover, this is not the Department's intent
- In light of the concerns raised about how this requirement could be applied, the Department proposes replacement of:
  - d) 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

    with…
  - d) not primarily for the convenience of the patient, physician, or other health care providers

Testimony at Hearing

- Advocacy for Patients with Chronic Illnesses, Inc.
- Connecticut Voices for Children
- Connecticut State Medical Society
- Connecticut Hospital Association
- National Multiple Sclerosis Society
- Connecticut Bar Association
- Keep the Promise Coalition
- Office of the Healthcare Advocate

Recurring Themes in Testimony

- Some past denials of services by MCOs were inappropriate and inconsistent with Medicaid regulation and policy.

  Response: Inappropriate denials sometimes occur. These denials are not related to the specifics of a medical necessity definition. They are addressed by DSS through education, contract enforcement and other measures. DSS intends to track and report all denials of services in a transparent manner and report regularly to the committee; inappropriate denials will be addressed accordingly.

Recurring Themes in Testimony

- The treatment of some health conditions is extremely complex, and finding the most effective drug regimen for a patient can be very difficult. The medical necessity review process needs to recognize the individual needs of those who suffer with those chronic conditions such as multiple sclerosis.

  Response: Understanding of the care of devastating illnesses, such as multiple sclerosis, and the use of biologics and other similar medications, is rapidly evolving. The Department's proposed definition seeks to respond to the evolution of care in a manner that accounts for both the rapid growth of clinical knowledge and clinical cost. Many of the drugs mentioned in the testimony are either on the PDL or are exempt from PA, so the new definition would not even be an issue. However, were PA to be introduced for these medications in the future, it would be by the recommendation of the independent Pharmacy and Therapeutics Committee or the Drug Utilization Review Board. Access to the drugs would also be permitted through the Department's PA approval process.

Recurring Themes in Testimony

- Only the treating physician has a true understanding of the patient's medical needs. The treating physician has the best interests of the patient in mind. Therefore, any decision maker must defer to the judgment of the treating physician as to what is medically necessary.

- Response: While the treating physician has the best knowledge of the patient's needs in a majority of cases, not all clinical decisions are made exclusively with the patient's needs in mind. For example, many of the nation's skyrocketing number of caesarean sections are planned surgeries before term. Are all of these surgeries performed with the newborn's needs in mind?

Recurring Themes in Testimony

- DSS' proposed definition, taken from the increasingly restrictive SAGA program, is neither patient- nor services-specific and is too expressly tied to cost reduction.

- Response: The department's proposed definition of medical necessity is the one used in the SAGA Program since 2006. Not one case of harm, inappropriate service denial or grievance has been presented from the SAGA Program.

Recurring Themes in Testimony

- Removing the requirement to pay for all services necessary to attain or maintain an optimal level of health establishes a standard of sub-optimal health care under Medicaid.
- Response: None of the key reference definitions (the American Medical Association, the American Dental Association, MA, NY, RI, or CT commercial) use the term "optimal." Certainly those widely used definitions do not support or allow suboptimal care. These other definitions support a reasonable standard of recovery, symptom control, and functioning based on generally accepted standards for the condition in question.

Conclusions

- Not one case or example was presented of a client harmed, inconvenienced, or otherwise negatively impacted by the proposed definition, in effect in the SAGA Program for the last five years
- All examples offered were potential harms; no examples of actual harm or service denials were offered
- All of the examples of necessary care would be considered medically necessary under the proposed definition, or could be coverable as a waiver service
- Examples of inappropriate Medicaid denials were under the current Medicaid medical necessity definition, and these were primarily coverage decisions rather than medical necessity decisions
- Many examples offered were from the commercial world or Medicare, such as the statement that "providers must jump through huge amounts of paperwork and frustration" to get medications approved

Definition Proposed by Medical Inefficiency Committee

Raised Bill 5296, AAC Definition of Medical Necessity

- "medically necessary" and "medical necessity" mean those services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate a medical condition or mental illness, or its effects, in order to attain or maintain maximum achievable health, functioning and independence, provided such services are:
  - (1) Consistent with generally-accepted standards of medical practice 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, as determined by the Department of Social Services;

Raised Bill 5296, AAC Definition of Medical Necessity

- (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the patient's illness, injury or disease; and
- (3) not primarily for the convenience of the patient, physician or other health care providers and 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 that patient's illness, injury or disease.

- (b) The Department of Social Services, or a designee of the department, shall conduct an individualized assessment of a Medicaid recipient's medical condition or mental illness to determine whether services are medically necessary or a medical necessity, as defined in subsection (a) of this section, for the recipient.

MIC Definition Maximum Achievable

- Maximum achievable is not present in any of the other reference definitions
  - –American Medical Association (AMA)
  - –American Dental Association (ADA)
  - –Medicare
  - –Massachusetts Medicaid
  - –New York Medicaid
  - –Rhode Island Medicaid
  - –Connecticut Commercial

MIC Definition
Maximum Achievable

- For many conditions, intervention may not be medically necessary according to generally accepted standards, even though the level of health or functioning is less than the maximum achievable.
- For example:
  - Salzmann scale in orthodontia; less than perfect teeth do not necessarily require intervention

MIC Definition
Maximum Achievable

- For many conditions, there is a generally accepted standard of success with respect to intervention, which may be less than the maximum achievable
- Examples:
  - Cholesterol management
  - Depression
  - Physical therapy and occupational therapy; substantial restoration based on a usual course of therapy, and not necessarily on maximum achievable
  - Low back pain
  - Scoliosis
- How can maximum achievement be measured? Who can determine?

MIC Definition
Independence

- An overarching purpose of the Medicaid program
- A consideration in design of Medicaid program benefits
- It is a broad construct rather than a specific, measurable standard for medical necessity determination
- It is not used in previously noted AMA, ADA, and other state Medicaid definitions

MIC Definition
Independence

- New standard requiring provision of all necessary services and supports for maximum achievable independence
- Creates an obligation beyond what may be reasonable and appropriate
- Examples:
  - Customized wheelchair
  - Crutches ($20) vs. roller aide ($400)

MIC Definition
Equivalent therapeutic or diagnostic result

- Equivalent is not defined for the purpose of this statute
- There is no formal mechanism to establish or assess therapeutic equivalence except in the area of pharmacy

MIC Definition
Equivalent therapeutic or diagnostic result

- In the absence of a method for establishing true equivalence, it may not be possible for the Department to establish a less costly alternative as therapeutically equivalent
- Example:
  - A physician recommends a four hour partial hospital program ($240/day)
  - Will the Department be able to deny authorization for the four hour partial hospital program, and instead authorize a three hour intensive outpatient program ($170/day)?
  - Assume there is nothing about this new behavioral health patient's presentation that would clearly indicate superior benefit of a four-hour program. Consider that a four-hour partial hospital program and a three-hour intensive outpatient program would not appear to be therapeutically equivalent under the strictest interpretation of the term…i.e., they are not of the same duration

MIC Definition
Equivalent therapeutic or diagnostic result

- In pharmacy, drug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.
- Drug products are considered to be therapeutically equivalent only if they are chemically identical

MIC Definition
Equivalent therapeutic or diagnostic result

- The demand for a non-PDL drug may be based on an initial treatment decision that is neither patient-centered nor clinically-driven
- Example A:
  - Free drug samples may lead to initial trial on new, substantially more costly drug, that is not based on individual consideration of the patient's needs.
  - When prior authorization is sought in the above case, will the Department be able to uphold denial of authorization for non-PDL drug, and require instead the PDL drug? The non-PDL drug is in the same therapeutic class and may be as likely to be effective, but it is not therapeutically equivalent

MIC Definition
Equivalent therapeutic or diagnostic result

- Example B:
  - Alternatively, a prescriber may simply prefer a non-PDL drug in most or all cases and such preference is not based on individual consideration as to whether the non-PDL drug would be likely to have the same effect.
  - When prior authorization is sought in the above case, will the Department be able to uphold denial of authorization for the non-PDL drug, and require instead the PDL drug? Here again, the non-PDL drug is in the same therapeutic class and may be as likely to be effective, but it is not therapeutically equivalent.
  - If the PDL drug was not effective or side effects were a problem, the non-PDL drug would be approved.

MIC Definition
Equivalent therapeutic or diagnostic result

- The Department covers removable dentures and does not cover fixed bridge or implant except in exceptional circumstances
- The proposed definition could make this limitation unenforceable
- Example:
  - 18 year old has lost two front teeth in a sports accident
  - Dentist recommends implants as a full functional replacement
  - CT DHP denies recommended service because partial denture would produce a comparable functional result, albeit neither an equivalent nor maximum achievable functional result.
  - Cost of partial denture – Approximate cost $1,200
  - Cost of implants – Approximate cost $10,000
  - Would this denial be upheld on appeal?

MIC Definition
Treating Physician Rule

- The Medical Inefficiency Committee intends that the proposed definition be applied consistent with the "treating physician rule"
- The treating physician rule is not the law in Connecticut and it is not the way that medical necessity review has been conducted in CT Medicaid
- If the treating physician rule were in effect, this would weaken the Department's ability to conduct effective medical necessity review and thereby reduce excessive, unnecessary, and inappropriate service use

MIC Definition
Fiscal Impact

- The proposed definition will not reduce inefficiency nor will it reduce the associated costs or harm to Medicaid recipients
- It will fail to achieve the $4 million in savings that were included in the appropriations act for SFY11
- Certain provisions would appear to result in millions of dollars in new costs to the Medicaid program on an annualized basis

Closing Comments

- Request the Medical Inefficiency Committee's support in combating excessive and unnecessary care
- Support a definition that addresses the problem of inefficiency
- Support a definition that affords the Department discretion and that recognizes that judgments of therapeutic value are inherently subjective
- Partner with the Department in monitoring the impact of the review process and medical necessity decisions on quality of care and inefficiency