Attn: M' Lori Ashby, M' Jyne Schafer

Dear M' Schafer,

Please read and feel free to forward my letter to all members of the DHMH & CMS **[PHI Redacted]** The Medicare and Medicaid manuals of coverage are grossly outdated in their science as it relates to GID, not to mention the overt discrimination resulting. The net effect is a failure to treat a treatable disorder which in many cases leads to death. The discrimination clearly un-American also opens the State and Federal Government to civil litigation and liability if left untended. The AMA as of 2008 have condemned the failure of CMS and public-private insurance to fund treatment . HHS, DHMH & CMS has a leadership role here, public insurance follows their lead on determination as I'm sure your aware . Action on this matter is long overdue **. [PHI Redacted]** This issue is too important to rely on a disabled patient alone to challenge this injustice. I have been working with several elected officials as well as CMC staffers but the burden always come to my door step. I want to make this happen but I need help from your office. **[PHI Redacted]** Please help me open a formal NCD to change Medicare NCD 140.3 to reflect the AMA res. 122. Also I would like to remain in the loop to insure a adequate redress to the matter. I would also ask for any and all data related to NCD 140.3 and any prior NCD's linked to this matter. **[PHI Redacted]** I would ask for any input from your office as to possible tasks needed to ensure patients are properly served. I firmly believe this a critical matter and free of political considerations as framed by the Social Security Act governing of medical ethics . I hope I can call on you for any question related in the future. Thank You, Nehael Jae

Enclosed please find: Personal letter / History , AMA Res 122, Medicare NCD 140.3, How to address NCD Matter guidance & NCD criteria guidance.

Dear Secretary Charles J Milligan Jr. ,

[PHI Redacted]

Thank You for listening.
Warmest Wishes, M' Nehael Jae Shields

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.26)
Coverage Determinations

Table of Contents
(Rev. 133, 07-08-11)

140.3 - Transsexual Surgery

(Rev. 1, 10-03-03)
CIM 35-61

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mammectomy, hysterectomy and salpingo-oophorectomy which may be followed by phalloplasty and the insertion of testicular prostheses. Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES
Resolution: 122 Of 2008
(A-08)

Introduced by: Resident and Fellow Section, Massachusettes Medical Society, California Medical Association, Medical Society of the State of New York

Subject: Removing Financial Barriers to Care for Transgender Patients

Referred to: Reference Committee A
Whereas, The

1 American Medical Association opposes discrimination on the basis of
2 gender identity1 and
3

Whereas, Gender Identity Disorder (GID) is a serious medical condition recognized as such in both the Diagnostic and Statistical Manual of Mental Disorders (4th Ed., Text Revision) (DSM-IV-TR) and the International Classification of Diseases (10th Revision),2 and is characterized in the DSM-IV-TR as a persistent discomfort with one's assigned sex and with one's primary and secondary sex characteristics, which causes intense emotional pain and suffering;3 and

Whereas, GID, if left untreated, can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death;4 and

Whereas, The World Professional Association For Transgender Health, Inc. ("WPATH") is the leading international, interdisciplinary professional organization devoted to the understanding and treatment of gender identity disorders,5 and has established internationally accepted Standards of Care 6 for providing medical treatment for people with GID, including mental health care, hormone therapy and sex reassignment surgery, which are designed to promote the health and welfare of persons with GID and are recognized within the medical community to be the standard of care for treating people with GID; and

Whereas, An established body of medical research demonstrates the effectiveness and medical necessity of mental health care, hormone therapy and sex reassignment surgery as forms of therapeutic treatment for many people diagnosed with GID; 7 and

Whereas, Health experts in GID, including WPATH, have rejected the myth that such treatments are "cosmetic" or "experimental" and have recognized that these treatments can provide safe and effective treatment for a serious health condition;7 and

Whereas, Physicians treating persons with GID must be able to provide the correct treatment necessary for a patient in order to achieve genuine and lasting comfort with his or her gender, based on the person's individual needs and medical history;8 and

Whereas, The AMA opposes limitations placed on patient care by third-party payers when such care is based upon sound scientific evidence and sound medical opinion;9, 10 and

Whereas, Many health insurance plans categorically exclude coverage of mental health, medical, and surgical treatments for GID, even though many of these same treatments, such as psychotherapy, hormone therapy, breast augmentation and removal, hysterectomy, oophorectomy, orchiectomy, and salpingectomy, are often covered for other medical conditions; and

Whereas, The denial of these otherwise covered benefits for patients suffering from GID represents discrimination based solely on a patient's gender identity; and

Whereas, Delaying treatment for GID can cause and/or aggravate additional serious and expensive health problems, such as stress-related physical illnesses, depression, and substance abuse problems, which further endanger patients' health and strain the health care system; therefore be it

RESOLVED, That the AMA support public and private health insurance coverage for treatment of gender identity disorder (Directive to Take Action); and be it further

RESOLVED, That the AMA oppose categorical exclusions of coverage for treatment of gender identity disorder when prescribed by a physician (Directive to Take Action).

Fiscal Note: No significant fiscal impact.

References

1. AMA Policy H-65.983, H-65.992, and H-180.980
2. Diagnostic and Statistical Manual of Mental Disorders (4th ed.. Text revision) (2000) ("DSM-IV-TR"), 576-82, American Psychiatric Association; International Classification of Diseases (10th Revision) ("ICD-10"), F64, World Health Organization. The ICD further defines transsexualism as "[a] desire to live and be accepted as a member of the opposite sex, usually accompanied by a sense of discomfort with, or inappropriateness of, one's anatomic sex, and a wish to have surgery and hormonal treatment to make one's body as congruent as possible with one's preferred sex." ICD-10, F64.0.
3. DSM-IV-TR, 575-79
4. Id. at 578-79.
5. World Professional Association for Transgender Health: http://www.wpath.org. Formerly known as The Harry Benjamin International Gender Dysphoria Association.
6. The Harry Benjamin International Gender Dysphoria Association's Standards of

Care for Gender Identity Disorders, Sixth Version (February, 2001). Available at http://wpath.org/Documents2/socv6.pdf.
7. Brown G R: A review of clinical approaches to gender dysphoria. J Clin Psychiatry. 51(2):57-64, 1990. Newfield E, Hart S, Dibble S, Kohler L. Female-to-male transgender quality of life. Qual Life Res. 15(9):1447-57, 2006. Best L, and Stein K. (1998) "Surgical gender reassignment for male to female transsexual people." Wessex Institute DEC report 88; Blanchard R, et al. "Gender dysphoria, gender reorientation, and the clinical management of transsexualism."J Consulting and Clinical Psychology. 53(3):295-304. 1985; Cole C, et al. "Treatment of gender

dysphoria (transsexualism)." Texas Medicine. 90(5):68-72. 1994; Gordon E. "Transsexual healing: Medicaid funding of sex reassignment surgery." Archives of Sexual Behavior. 20(1):61-74. 1991; Hunt D, and Hampton J. "Follow-up of 17 biologic male transsexuals after sex-reassignment surgery." Am J Psychiatry. 137(4):432-428. 1980; Kockett G, and Fahrner E. "Transsexuals who have not undergone surgery: A follow-up study." Arch of Sexual Behav. 16(6):511-522. 1987; Pfafflin F and Junge A. "Sex Reassignment. Thirty Years of International Follow-Up Studies after Sex Reassignment Surgery: A Comprehensive Review, 1961-1991." IJT Electronic Books, available at http://www.symposion.com/ijt/pfaefflin/1000.htm; Selvaggi G, et al. "Gender Identity Disorder: General Overview and Surgical Treatment for Vaginoplasty in Male-to-Female Transsexuals." Plast Reconstr Surg. 2005 Nov;116(6):135e-145e; Smith Y, et al. "Sex reassignment: outcomes and predictors of treatment for adolescent and adult transsexuals." Psychol Med. 2005 Jan; 35(1):89-99; Tangpricha V, et al. "Endocrinologic treatment of gender identity disorders. " Endocr Pract. 9(1):12-21. 2003; Tsoi W. "Follow-up study of transsexuals after sex reassignment surgery." Singapore Med J. 34:515-517. 1993; van Kesteren P, et al. "Mortality and morbidity in transsexual subjects treated with cross-sex hormones." Clin Endocrinol (Oxf). 1997 Sep;47(3):337-42; World Professionals Association for Transgender Health Standards of Care for the Treatment of Gender Identity Disorders v.6 (2001).
8. The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders, at 18.
9. Id.
10. AMA Policy H-120.988

Relevant AMA policy

H-65.983 Nondiscrimination Policy
The AMA opposes the use of the practice of medicine to suppress political dissent wherever it may occur. (Res. 127, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CEJA Rep. 2, A-05)

H-65.992 Continued Support of Human Rights and Freedom
Our AMA continues (1) to support the dignity of the individual, human rights and the sanctity of human life, and (2) to oppose any discrimination based on an individual's sex, sexual orientation, race, religion, disability, ethnic origin, national origin or age and any other such reprehensible policies. (Sub. Res. 107, A-85; Modified by CLRPD Rep. 2, I-95; Reaffirmation A-00; Reaffirmation A-05)

H-180.980 Sexual Orientation as Health Insurance Criteria
The AMA opposes the denial of health insurance on the basis of sexual orientation. (Res. 178, A-88; Reaffirmed: Sub. Res. 101, I-97)

H-120.988 Patient Access to Treatments Prescribed by Their Physicians
The AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an unlabeled indication when such use is based upon

sound scientific evidence and sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as reasonable and necessary medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate "off-label" uses of drugs on their formulary. (Res. 30, A-88; Reaffirmed: BOT Rep. 53, A-94; Reaffirmed and Modified by CSA Rep. 3, A-97; Reaffirmed and Modified by Res. 528, A-99; Reaffirmed: CMS Rep. 8, A-02; Reaffirmed: CMS Rep. 6, A-03; Modified: Res. 517, A-04)

Date:
04/11/2006
Public Comment Period:
N/A - N/A

Guidance for the Public, Industry and CMS Staff
Factors CMS Considers in Opening a
National Coverage Determination
Document Issued: April 11, 2006

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For questions regarding the National Coverage Determination Process, please contact Vadim Lubarsky, at (410) 786-0840.

Guidance for the Public, Industry and CMS Staff
Factors CMS Considers in Opening a National Coverage Determination

I. Purpose of this Guidance Document

The purpose of this guidance document is to relate the factors CMS considers for opening a National Coverage Determination (NCD). This guidance document details:
1) the initial portion of the NCD process; and 2) what CMS considers a complete, formal request necessary to start the formal review process. These procedures relate to the September 26, 2003 Federal Register Notice on the coverage process (68 Fed Reg. 55634) and describe our current thinking regarding these processes. We have taken steps to make the process more collaborative and predictable. We will be posting potential NCD topics to the coverage web site and are encouraging stakeholder comments on potential topics. We have also made several other explanatory changes throughout the document.

II. Background

This is a guidance document required under section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which requires the Secretary to make available to the public the factors considered in making national coverage determinations (NCDs) of whether an item or service is reasonable and necessary. For additional information on the background of the Medicare program or on the overall coverage process, please consult the September 26, 2003 Federal Register Notice on the Process for Making Medicare National Coverage Determinations.

III. Prior to Initiation

The NCD process consists of three major steps: 1) initiation, 2) review, and 3) completion. CMS initiates the NCD process by "opening" the NCD. This is announced to the public by posting a "tracking sheet" on the CMS coverage web site. NCD reviews pertain to reviews of particular items and services to determine whether they meet the statutory requirements. Development of a complete, formal request for an NCD can be initiated either by an outside party or internally by CMS staff.

Though requestors and other interested parties are encouraged to provide additional information, clarify issues, and engage in dialogue as questions arise during the development of an NCD, the NCD is likely to be developed and completed in the most timely manner when relevant information is provided with the initial request. A key goal of publishing guidance documents is to help describe and define the relevant information on which an efficient NCD rests, as well as describe the factors we consider in determining whether an item or service is reasonable and necessary. Therefore, we believe it is important to describe our approach to evaluating the scientific information submitted, and what constitutes adequate evidence to support NCD development.

A. Informal contacts and inquiries

The public frequently raises general questions about the coverage of items and services to us by telephone, mail, or in person. These questions may include, but are not limited to, asking us to explain the current coverage of a particular item or service, or requesting assistance with, or advice about, possible submission of a formal request for an NCD. We consider all of these contacts to be informal and will not announce the substance of these contacts on our web site. These inquiries will not normally trigger the national coverage process until a formal request is submitted by a requestor; however, CMS is not precluded from performing additional research on topics discussed during these inquiries and may elect to initiate the NCD process under its own initiative.

If requested, CMS will advise interested parties on how to request an NCD, the implications of such a request, and explain what is needed for us to consider a submission to be a complete, formal request. We will offer suggestions to the requestor to clarify the amount and kind of information necessary for us to evaluate whether an item or service is "reasonable and necessary" under the Act, and in some instances, we may provide assistance to the requestor in meeting this threshold by assisting them in locating relevant evidence.

B. Preliminary meetings

Preliminary discussions are encouraged for requestors to discuss issues that may affect review of their requests. These meetings, either in person or by teleconference, are useful to conserve both industry and government resources in avoiding duplicative work and to assure that all relevant evidence is submitted in a timely manner. The following are some suggested topics that requestors may wish to discuss at these meetings:

- Supporting documentation related to the request;
- Clinical trial data;
- Short- and long-term action items that stakeholders may adopt;
- Expectations of evidence in the process; and
- Information on the applicability of the item or service in question to the Medicare population.

CMS, in turn, may:

- Discuss components and concepts of the NCD process, including but not limited to, benefit category determination, the NCD timeline, evidence-based medicine, local vs. national coverage determinations, FDA and CMS relationships, and other items;
- Provide initial evaluation of supporting documentation presented by the requestor;
- Provide initial information on the likely scope of the review and assessment questions;
- Provide initial opinions on the applicability of the item or service in question to the Medicare population; and
- Provide information on the complete NCD process.

Preliminary discussions will not always lead to the initiation of an NCD. Furthermore, while meetings with stakeholders are not confidential, we will attempt to protect the confidentiality of any documents submitted during these meetings to the extent permitted by law, and will not post the substance of preliminary meetings.

IV. Who Can Request an NCD

Development of a complete, formal request for an NCD can be initiated either by an outside party or by internal Agency personnel.

A. Requests by external parties

A request to make an NCD can be received from an individual or entity who identifies an item or service as a potential benefit (or to prevent potential harm) to Medicare beneficiaries. A requestor may be a Medicare beneficiary, manufacturer, provider, supplier, medical professional association, health plan, or other party who requests our consideration of a particular issue for an NCD. In certain cases (e.g., an individual layperson), a requestor may not have the resources to identify evidence needed to meet the reasonable and necessary standard. In these rare cases, we may assist the requestor in locating the necessary evidence.

B. Requests by aggrieved parties

Section 1869(f)(4) of the Social Security Act permits certain aggrieved persons to make a request that the Secretary issue a national coverage or noncoverage determination with respect to a particular type or class of items or services, if the Secretary had not previously made a coverage or noncoverage determination. These individuals are described in section 1869(f)(5) of the Act as "individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need of the item or service that is the subject of the coverage determination." Thus, this track can be invoked only for an initial request if we have not issued a coverage or noncoverage NCD.

We realize that in these very rare instances related to requests made by aggrieved parties, the statute establishes specific time deadlines and we will notify the requestors when these situations arise.

C. Requests initiated internally

National Coverage Determinations are discussed in sections 1862, 1869, and 1871 of the Social Security Act. We may internally generate a request to develop an NCD in the interest of the general health and safety of Medicare beneficiaries. Generally, once initiated, this process is similar to the externally-generated request process.

The following are circumstances that may prompt CMS to generate an internal NCD request on an existing technology already in use:

- Providers, patients or other members of the public have raised significant questions, that are supported by CMS’s initial review of available data, about the health benefits of currently covered items or services, specifically regarding the Medicare population;
- Interpretation of new evidence or re-interpretation of previously available evidence indicates that changes may be warranted in current policies;
- Local coverage policies are inconsistent or conflict with each other to the detriment of Medicare beneficiaries. For instance, the noted variation is not related to local differences in the capabilities of health care providers to use the technology effectively which can be resolved over time, but rather is causing significant disparities in the care available to Medicare beneficiaries that are unlikely to be addressed effectively through provider training and education or through the local coverage process;
- Program integrity concerns have arisen under existing local or national policies; that is, there is significant evidence of wide variation in billing practices not related to variation in clinical need, or of potential for fraud under existing policies.

An internally-generated NCD may also be considered for a new item or service, an existing item or service that has been substantially modified, or for a proposed new use of a covered product if:

- The health technology represents a substantial clinical advance and is likely to result in a significant health benefit if it diffuses more rapidly to all patients for whom it is indicated.
- More rapid diffusion of the technology is likely to have a significant programmatic impact on Medicare and on other Medicare-related public policies (e.g., reduction in health inequalities).
- Significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology. The presence of significant uncertainty about benefits and risks is of particular concern when rapid diffusion of the item or service is likely when:
    - Use of the new item or service likely conflicts with existing NCDs.
    - Available evidence suggests that local variation is not warranted.

Cost effectiveness is not a factor CMS considers in making NCDs. In other words, the cost of a particular technology is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population through an NCD.
Before deciding whether to generate an NCD, CMS may consult with relevant beneficiary groups, professional bodies and/or manufacturers of the technologies in question using the public comment function available on the coverage web site. Specifically, we will usually announce potential topics that are being considered for internally-generated requests on our web site on a quarterly basis, and allow interested stakeholders to comment on these topics. The purpose of these announcements is both to enable interested parties to provide any additional information as well as comments. Furthermore, these announcements will provide advance notice to the public regarding potential topics that we are considering, and allow stakeholders to suggest additional topics for consideration, creating a more transparent and predictable NCD process.
The public is encouraged to comment on potential topics and provide relevant evidence on whether a review should or should not proceed prior to the formal decision to open an NCD. We are attempting to balance the public's desire to comment extensively on potential topics with the inherent resource and time constraints in the NCD process. Due to these resource and time constraints, the public comment function available on the coverage web site will be the primary tool used to solicit input regarding this stage of the NCD process; stakeholders bear the responsibility for reviewing the quarterly list and submitting comments or evidence that they believe to be relevant.

V. What Constitutes a Complete, Formal Request for an NCD

There are several ways an individual or entity can contact us about NCDs. One approach involves informal contacts, as described above. The other approach involves "formal requests," and may result in the official opening of an NCD.
The latter process will be initiated when we receive a complete, formal request. A request is considered to be "received" once certain conditions are met. These conditions include:

- A formal request letter and supporting documentation submitted electronically (unless there is good cause for only a hardcopy submission).
- The request is identified as a "formal request for an NCD."
- The request states the benefit category or categories of the Medicare program to which the requestor believes the item or service applies. Examples of benefit categories include durable medical equipment, physician services, inpatient hospital services, and

diagnostic tests. The requestor may recommend one or more benefit categories for the item or service and submit supporting documentation justifying the recommendation. All the information needed to make a benefit category determination, (including that provided by the requestor and generated by the agency) should be in place before the request can be considered complete. In instances when ambiguity may exist, CMS will need to carefully analyze whether the item or service falls under a benefit category determination before opening an NCD in order to ensure that there is an applicable statutory category. If an item or service can fit into more than one benefit category, we have the discretion to assign it to the most appropriate one.

- The requestor should submit adequate supporting documentation along with the formal letter, including a full compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service. Additional information on documentation will be discussed in the guidance document on evidentiary standards.

After we receive a request for an NCD and determine that the requested item or service requires a benefit category determination from the Center for Medicare Management (CMM), we forward a copy of the request and appropriate supporting documentation to CMM. CMM reviews the materials supplied by the Coverage and Analysis Group (CAG) in addition to any other relevant information to determine whether the Social Security Act provides a benefit category for the item or service.

Local coverage is not pre-empted simply by the initiation of an NCD or a request for a technology assessment or Medicare Coverage Advisory Committee review. Opening an NCD does not change local coverage policies. Once a final NCD is issued local contractors must amend or withdraw any inconsistent LCDs.

VI. CMS Review of a Formal Request

When a requestor submits a request for an NCD, we review the materials to determine if it meets the definition of a complete, formal request. If the request lacks adequate supporting documentation to enable us to conduct our review, we notify the requestor and explain our rationale. For instance, we may advise the requestor that the quality of the evidence appears limited. However, we will not decline a request simply because the evidence presented seems insufficient.

Requestors are encouraged to schedule and complete a preliminary meeting with the appropriate CAG personnel. At this meeting, a preliminary review of the item or service and supporting documentation can be presented by the requestor, and any additional information that might be necessary can be requested by CAG personnel. Preliminary meetings are also the appropriate place for the requestor to submit clinical trial protocols for review, if relevant.

Once the request is considered “received,” we post the request on our web site under our list of pending coverage issues. Posting of the tracking sheets permits interested individuals to participate in and monitor the progress of the NCD process. This is a key element in making our NCD process more efficient, open, and accessible to the public. Once a formal request is posted, there will be additional opportunities for public participation and submission of additional evidence (such as the initial 30-day comment period and 30-day comment period on the draft NCD).

We continue to expect that a requestor will submit all evidence currently available pertaining to the issue of whether the item or service is reasonable and necessary. In the absence of adequate evidence, we may conclude that the item or service is not reasonable and necessary or leave the issue for local contractor discretion.

VII. Proprietary Data

In section 1862(a)(in the matter following (22)) of the Act, the Congress provided that the Secretary was not required to disclose “proprietary data” to the public when making available

the data considered in making the determination. This exception serves to encourage manufacturers and others to submit evidence that would be useful in making NCDs. Prior to this statute, manufacturers may have been reluctant to submit valuable business and commercial data if they believed it would be publicly disclosed as part of a record in a judicial proceeding. This provision enables the Secretary to receive and consider proprietary data and to assure that proprietary data will not be disclosed except as required by law. Our ability to obtain proprietary data may enable us to develop NCDs, including determinations that may expand Medicare coverage, more rapidly and accurately.

We believe the statutory protection accorded proprietary data ensures the availability of the best relevant information, and maximizes flexibility in developing coverage determinations.

VIII. Prioritizing Requests

In the rare event that we have a large volume of NCD requests to review at once, we retain the flexibility to prioritize these requests based on the magnitude of the impact on the Medicare program and beneficiaries. This flexibility will enable us to ensure that we can pay priority attention to those requests that have potential for significant impact on our beneficiaries—a life-saving cancer treatment, a breakthrough in cardiac pacing, etc.

IX. Role of the Council on Technology and Innovation (CTI)

While not a direct component of the NCD process, the CTI allows better coordination of the NCD process and coverage issues across CMS. The CTI is comprised of senior level CMS leaders and experts on clinical, coverage and payment issues. The Council's mission is to provide CMS with improved methods for developing practical information about the clinical benefits of new medical technologies resulting in faster and more efficient coverage and payment of these medical technologies. Through the Council's efforts, CMS is better able to coordinate the coverage process with other related activities, such as payment and coding.

X. Where to Submit a Complete Formal Request

Electronic requests may be submitted via the coverage web site using the "Contact Us" link. Requests may also be submitted in electronic format by mail to: Centers for Medicare and Medicaid Services; Director, Coverage and Analysis Group; 7500 Security Blvd.; Baltimore, MD 21244.

XI. Conclusion

Proper application of the principles and procedures outlined in this guidance document can promote public health and access by speeding the development of NCDs, and can assure that NCDs are both accurate and timely.

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CAGInquiries@cms.hhs.gov
CAGInquiries@cms.hhs.gov

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Dear M' Feild ,

Enclosed please find information I found to answer my own question on Friday as to Who receives formal NCD requests. This information posses a new question however . " How or can one request CMS NCD data in present determination **Medicare National Coverage Determinations Manual Chapter 1, Part 2140.3 - Transsexual Surgery (Rev. 1, 10-03-03) CIM 5-61 140.3 - Transsexual**

Surgery any prior requests" This collection of data would be helpful as to not duplicate data to be found or submitted to a formal request.. This request would also show just how deeply CMS questioned the original determination and will indicate a threshold that must be met in order to overturn the present findings. I would in the end hope CMS would assist me in developing a sound NCD formal request? I also believe a body of evidence rests in the AMA's determination of Resolution 122. This plus my own case and CMS data on this issue prior is a sound base for a NCD review of determinations past and looking forward. Thank You again for the Federal register documents you forwarded to me. They did help! They guided me to a better understanding of my path through this jungle of requirements and hopefully finding the funding necessary to **[PHI Redacted].** Like I have indicated before this illness if life threatening so please be patient with my passionate determination. I want there to be no misunderstanding this is a question of funding not science. The science is clear and effective all that we need is the attention of CMS.

Best Wishes, Ms Nehael Jae Shields

Date:
04/11/2006
Public Comment Period:
N/A - N/A

Guidance for the Public, Industry and CMS Staff
Factors CMS Considers in Opening a
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This guidance represents the Centers for Medicare & Medicaid Services' (CMS's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind CMS or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, we encourage you to contact CMS staff listed on the title page of this guidance.

I. Purpose of this Guidance Document

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A. Informal contacts and inquiries

The public frequently raises general questions about the coverage of items and services to us by telephone, mail, or in person. These questions may include, but are not limited to, asking us to explain the current coverage of a particular item or service, or requesting assistance with, or advice about, possible submission of a formal request for an NCD. We consider all of these contacts to be informal and will not announce the substance of these contacts on our web site. These inquiries will not normally trigger the national coverage process until a formal request is submitted by a requestor; however, CMS is not precluded from performing additional research on topics discussed during these inquiries and may elect to initiate the NCD process under its own initiative.

If requested, CMS will advise interested parties on how to request an NCD, the implications of such a request, and explain what is needed for us to consider a submission to be a complete, formal request. We will offer suggestions to the requestor to clarify the amount and kind of information necessary for us to evaluate whether an item or service is "reasonable and necessary" under the Act, and in some instances, we may provide assistance to the requestor in meeting this threshold by assisting them in locating relevant evidence.

B. Preliminary meetings

Preliminary discussions are encouraged for requestors to discuss issues that may affect review of their requests. These meetings, either in person or by teleconference, are useful to conserve both industry and government resources in avoiding duplicative work and to assure that all relevant evidence is submitted in a timely manner. The following are some suggested topics that requestors may wish to discuss at these meetings:

- Supporting documentation related to the request;
- Clinical trial data;
- Short- and long-term action items that stakeholders may adopt;
- Expectations of evidence in the process; and
- Information on the applicability of the item or service in question to the Medicare population.

CMS, in turn, may:

- Discuss components and concepts of the NCD process, including but not limited to, benefit category determination, the NCD timeline, evidence-based medicine, local vs. national coverage determinations, FDA and CMS relationships, and other items;
- Provide initial evaluation of supporting documentation presented by the requestor;
- Provide initial information on the likely scope of the review and assessment questions;
- Provide initial opinions on the applicability of the item or service in question to the Medicare population; and
- Provide information on the complete NCD process.

Preliminary discussions will not always lead to the initiation of an NCD. Furthermore, while meetings with stakeholders are not confidential, we will attempt to protect the confidentiality of any documents submitted during these meetings to the extent permitted by law, and will not post the substance of preliminary meetings.

IV. Who Can Request an NCD

Development of a complete, formal request for an NCD can be initiated either by an outside party or by internal Agency personnel.

A. Requests by external parties

A request to make an NCD can be received from an individual or entity who identifies an item or service as a potential benefit (or to prevent potential harm) to Medicare beneficiaries. A requestor may be a Medicare beneficiary, manufacturer, provider, supplier, medical professional association, health plan, or other party who requests our consideration of a particular issue for an NCD. In certain cases (e.g., an individual layperson), a requestor may not have the resources to identify evidence needed to meet the reasonable and necessary standard. In these rare cases, we may assist the requestor in locating the necessary evidence.

B. Requests by aggrieved parties

Section 1869(f)(4) of the Social Security Act permits certain aggrieved persons to make a request that the Secretary issue a national coverage or noncoverage determination with respect to a particular type or class of items or services, if the Secretary had not previously made a coverage or noncoverage determination. These individuals are described in section 1869(f)(5) of the Act as "individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need of the item or service that is the subject of the coverage determination." Thus, this track can be invoked only for an initial request if we have not issued a coverage or noncoverage NCD.

We realize that in these very rare instances related to requests made by aggrieved parties, the statute establishes specific time deadlines and we will notify the requestors when these situations arise.

C. Requests initiated internally

National Coverage Determinations are discussed in sections 1862, 1869, and 1871 of the Social Security Act. We may internally generate a request to develop an NCD in the interest of the general health and safety of Medicare beneficiaries. Generally, once initiated, this process is similar to the externally-generated request process.

The following are circumstances that may prompt CMS to generate an internal NCD request on an existing technology already in use:

- Providers, patients or other members of the public have raised significant questions, that are supported by CMS’s initial review of available data, about the health benefits of currently covered items or services, specifically regarding the Medicare population;

- Interpretation of new evidence or re-interpretation of previously available evidence indicates that changes may be warranted in current policies;
- Local coverage policies are inconsistent or conflict with each other to the detriment of Medicare beneficiaries. For instance, the noted variation is not related to local differences in the capabilities of health care providers to use the technology effectively which can be resolved over time, but rather is causing significant disparities in the care available to Medicare beneficiaries that are unlikely to be addressed effectively through provider training and education or through the local coverage process;
- Program integrity concerns have arisen under existing local or national policies; that is, there is significant evidence of wide variation in billing practices not related to variation in clinical need, or of potential for fraud under existing policies.

An internally-generated NCD may also be considered for a new item or service, an existing item or service that has been substantially modified, or for a proposed new use of a covered product if:

- The health technology represents a substantial clinical advance and is likely to result in a significant health benefit if it diffuses more rapidly to all patients for whom it is indicated.
- More rapid diffusion of the technology is likely to have a significant programmatic impact on Medicare and on other Medicare-related public policies (e.g., reduction in health inequalities).
- Significant uncertainty exists concerning the health benefits, patient selection, or appropriate facility and staffing requirements for the new technology. The presence of significant uncertainty about benefits and risks is of particular concern when rapid diffusion of the item or service is likely when:
    - Use of the new item or service likely conflicts with existing NCDs.
    - Available evidence suggests that local variation is not warranted.

Cost effectiveness is not a factor CMS considers in making NCDs. In other words, the cost of a particular technology is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population through an NCD.
Before deciding whether to generate an NCD, CMS may consult with relevant beneficiary groups, professional bodies and/or manufacturers of the technologies in question using the public comment function available on the coverage web site. Specifically, we will usually announce potential topics that are being considered for internally-generated requests on our web site on a quarterly basis, and allow interested stakeholders to comment on these topics. The purpose of these announcements is both to enable interested parties to provide any additional information as well as comments. Furthermore, these announcements will provide advance notice to the public regarding potential topics that we are considering, and allow stakeholders to suggest additional topics for consideration, creating a more transparent and predictable NCD process.
The public is encouraged to comment on potential topics and provide relevant evidence on whether a review should or should not proceed prior to the formal decision to open an NCD. We are attempting to balance the public's desire to comment extensively on potential topics with the inherent resource and time constraints in the NCD process. Due to these resource and time constraints, the public comment function available on the coverage web site will be the primary tool used to solicit input regarding this stage of the NCD process; stakeholders bear the responsibility for reviewing the quarterly list and submitting comments or evidence that they believe to be relevant.

V. What Constitutes a Complete, Formal Request for an NCD

There are several ways an individual or entity can contact us about NCDs. One approach involves informal contacts, as described above. The other approach involves "formal requests," and may result in the official opening of an NCD.
The latter process will be initiated when we receive a complete, formal request. A request is considered to be “received” once certain conditions are met. These conditions include:

- A formal request letter and supporting documentation submitted electronically (unless there is good cause for only a hardcopy submission).
- The request is identified as a "formal request for an NCD."
- The request states the benefit category or categories of the Medicare program to which the requestor believes the item or service applies. Examples of benefit categories include durable medical equipment, physician services, inpatient hospital services, and diagnostic tests. The requestor may recommend one or more benefit categories for the item or service and submit supporting documentation justifying the recommendation. All the information needed to make a benefit category determination, (including that provided by the requestor and generated by the agency) should be in place before the request can be considered complete. In instances when ambiguity may exist, CMS will need to carefully analyze whether the item or service falls under a benefit category determination before opening an NCD in order to ensure that there is an applicable statutory category. If an item or service can fit into more than one benefit category, we have the discretion to assign it to the most appropriate one.
- The requestor should submit adequate supporting documentation along with the formal letter, including a full compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service. Additional information on documentation will be discussed in the guidance document on evidentiary standards.

After we receive a request for an NCD and determine that the requested item or service requires a benefit category determination from the Center for Medicare Management (CMM), we forward a copy of the request and appropriate supporting documentation to CMM. CMM reviews the materials supplied by the Coverage and Analysis Group (CAG) in addition to any other relevant information to determine whether the Social Security Act provides a benefit category for the item or service.
Local coverage is not pre-empted simply by the initiation of an NCD or a request for a technology assessment or Medicare Coverage Advisory Committee review. Opening an NCD does not change local coverage policies. Once a final NCD is issued local contractors must amend or withdraw any inconsistent LCDs.

VI. CMS Review of a Formal Request

When a requestor submits a request for an NCD, we review the materials to determine if it meets the definition of a complete, formal request. If the request lacks adequate supporting documentation to enable us to conduct our review, we notify the requestor and explain our rationale. For instance, we may advise the requestor that the quality of the evidence appears limited. However, we will not decline a request simply because the evidence presented seems insufficient.
Requestors are encouraged to schedule and complete a preliminary meeting with the appropriate CAG personnel. At this meeting, a preliminary review of the item or service and supporting documentation can be presented by the requestor, and any additional information that might be necessary can be requested by CAG personnel. Preliminary meetings are also the appropriate place for the requestor to submit clinical trial protocols for review, if relevant.
Once the request is considered “received,” we post the request on our web site under our list of pending coverage issues. Posting of the tracking sheets permits interested individuals to

participate in and monitor the progress of the NCD process. This is a key element in making our NCD process more efficient, open, and accessible to the public. Once a formal request is posted, there will be additional opportunities for public participation and submission of additional evidence (such as the initial 30-day comment period and 30-day comment period on the draft NCD).

We continue to expect that a requestor will submit all evidence currently available pertaining to the issue of whether the item or service is reasonable and necessary. In the absence of adequate evidence, we may conclude that the item or service is not reasonable and necessary or leave the issue for local contractor discretion.

VII. Proprietary Data

In section 1862(a)(in the matter following (22)) of the Act, the Congress provided that the Secretary was not required to disclose "proprietary data" to the public when making available the data considered in making the determination. This exception serves to encourage manufacturers and others to submit evidence that would be useful in making NCDs. Prior to this statute, manufacturers may have been reluctant to submit valuable business and commercial data if they believed it would be publicly disclosed as part of a record in a judicial proceeding. This provision enables the Secretary to receive and consider proprietary data and to assure that proprietary data will not be disclosed except as required by law. Our ability to obtain proprietary data may enable us to develop NCDs, including determinations that may expand Medicare coverage, more rapidly and accurately.

We believe the statutory protection accorded proprietary data ensures the availability of the best relevant information, and maximizes flexibility in developing coverage determinations.

VIII. Prioritizing Requests

In the rare event that we have a large volume of NCD requests to review at once, we retain the flexibility to prioritize these requests based on the magnitude of the impact on the Medicare program and beneficiaries. This flexibility will enable us to ensure that we can pay priority attention to those requests that have potential for significant impact on our beneficiaries—a life-saving cancer treatment, a breakthrough in cardiac pacing, etc.

IX. Role of the Council on Technology and Innovation (CTI)

While not a direct component of the NCD process, the CTI allows better coordination of the NCD process and coverage issues across CMS. The CTI is comprised of senior level CMS leaders and experts on clinical, coverage and payment issues. The Council's mission is to provide CMS with improved methods for developing practical information about the clinical benefits of new medical technologies resulting in faster and more efficient coverage and payment of these medical technologies. Through the Council's efforts, CMS is better able to coordinate the coverage process with other related activities, such as payment and coding.

X. Where to Submit a Complete Formal Request

Electronic requests may be submitted via the coverage web site using the "Contact Us" link. Requests may also be submitted in electronic format by mail to: Centers for Medicare and Medicaid Services; Director, Coverage and Analysis Group; 7500 Security Blvd.; Baltimore, MD 21244.

XI. Conclusion

Proper application of the principles and procedures outlined in this guidance document can promote public health and access by speeding the development of NCDs, and can assure that NCDs are both accurate and timely.