

## Medical Care if Necessary, But Not Necessarily Medical Care

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The purpose of this article is to show that current cancer care funding policy, particularly for some new and costly cancer drugs, fails to comply with a fundamental principle of the *Canada Health Act*, namely, that no one should suffer catastrophic financial loss as a result of a disease or a disability. The preamble to the *Canada Health Act* establishes the principle that the Parliament of Canada recognizes that "...continued access to quality health care without financial or other barriers will be critical to maintaining and improving the health and well-being of Canadians..." Accessibility and comprehensiveness are two of the five key principles set out in the *Act*.

This article also shows that where funding is not provided on the basis that the proposed drug or therapy is "not medically necessary", the failure to fund not only creates financial hardship for patients, but the words that describe the rationale for non-funding, namely, that the drug or therapy is "not medically necessary", also cause emotional hardship. Even more troubling, the use of the words "not medically necessary" masks the failure of non-funding provinces to comply with the *Canada Health Act*.

The *Canada Health Act* establishes a legislative scheme whereby the federal government makes cash contributions to those provinces and territories which establish health care insurance plans which meet the criteria of public administration, comprehensiveness, universality, portability and accessibility. The federal government may withhold or reduce funding for those provinces whose plans fail to meet the criteria.

To be eligible for the cash contribution the provinces and territories must provide health care services including hospital services. Hospital services are defined in the *Act* as those services which are "...medically necessary for the purpose of maintaining health, preventing disease or diagnosing or treatment an injury, illness or disability, namely: ...

- laboratory and radiological and other diagnostic procedures; and
- drugs, biologicals and related preparations when administered in the hospital;....

but does not include services that are excluded by the regulations."

There are no regulations under the *Canada Health Act* excluding services. There is a regulation requiring disclosure of information related to extra billing and user charges, SRO/86-259.

Many health care services are now available which are not within the definition of "insured health services", in particular, some cancer drugs which are not provided in a hospital setting. There is no obligation under the *Canada Health Act* for provincial and territorial health insurance plans to fund these drugs or therapies.

But the critical question raised by the *Canada Health Act* definition of "insured health services" is what services are "medically necessary"?

The *Canada Health Act* does not define the term "medically necessary" but Health Canada does discuss the term in its annual report on provincial compliance with the *Act*. Section 23 of the *Act* requires the provinces to report to Parliament each year on the extent to which each provincial health care insurance plan has satisfied the criteria under the *Act*. The glossary to the *Canada Health Act* annual reports prepared by Health Canada includes this definition of "medical necessity":

"Under the *Canada Health Act* the provincial and territorial governments are required to provide medically necessary hospital and physician services to their residents on a prepaid basis, and on uniform terms and conditions. The *Act* does not define medical necessity. The provincial and territorial health insurance plans, in consultation with their respective physician colleges or groups, are responsible for determining which services are medically necessary for health insurance purposes. If it is determined that a service is medically necessary, the full cost of the service must be covered by the public insurance plan to be in compliance with the *Act*. If a service is not considered to be medically required, the province or territory need not cover it through its health insurance plan".

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The *Canada Health Act* requires provincial and territorial health insurance plans to consult with physicians. But the consultation process does not mean that the provincial and territorial health insurance plans are obliged to defer to physicians. For example, Cancer Care Ontario's Disease Site Groups make specific recommendations for CCO oncologists about which treatments to use based on an extensive review of clinical evidence, and CCO oncologists also participate on an oncology subcommittee of the Ministry's Committee to Evaluate Drugs. There have been many examples of the Ontario Ministry of Health and Long-Term Care deciding not to fund treatments because of cost even as the provincial cancer system recommends those treatments as the standard of care.

Thus Health Canada's definition gives the provincial and territorial health insurance plans broad discretion to determine which services are "medically necessary" for health insurance purposes. While the criterion for the exercise of this discretion appears to relate to medical or clinical issues, in reality the provinces have discretion to define "medically necessary" in the light of financial constraints, funding or cost effectiveness as determined by the province or territory as a matter of funding policy.

The form of words used to limit what is "medically necessary" are the words "prescribed as medically necessary" or "prescribed medically necessary service".

For example section 12 of the *Ontario Health Insurance Act* describes "insured services" as "...every insured person is entitled to payment....for....insured services in the amounts and subject to such conditions and co-payments, if any, as are prescribed."

The "prescribed" services are set out in Regulation 552 made under the *Health Insurance Act*. Other provinces have enacted similar legislation and regulations. In determining whether or not a service is to be or is not to be "prescribed", the provinces, in practice, take into account funding and cost effectiveness in addition to the medical worth of the service. But the use of the nearly identical terms "medically necessary" and "prescribed medically necessary services" may easily create confusion.

Colleen M. Flood<sup>1</sup>, notes that "provincial governments have availed themselves of the latitude provided by the failure to define "medically necessary" in the Act and engage in "explicit rationing" and adds that they have done this by delisting certain services, ie., removed them from the list of services that are publicly funded. In the case of failure to fund new cancer drugs and therapies, the issue is not "delisting" but whether a new therapy will be listed at all.

The confusing use of the terms "medically necessary" and "prescribed medically necessary services", particularly as a rationale for funding decisions, raises four critical issues:

First, the distinction between "prescribed medically necessary services" and "medically necessary services" is unnecessarily confusing and a cause of unnecessary emotional hardship for patients and families who have not had "medically necessary services" funded despite, in some cases, assurance from their medical team that the service is clinically effective.

Second, the confusion and hardship is inevitably worsened when patients become aware of differences in funding among the provinces. When a patient is advised by his or her medical team that a service is "medically necessary" (on medical grounds) but is unfunded in the patient's home province, it can only be frustrating and bewildering for that same patient to learn that the same service is "medically necessary" (on medical grounds) and is funded in another province. Would it not be far better for a provincial or territorial health insurance plan to clearly state that while a service may be "medically necessary" on medical grounds the province or territory deems it a service too costly for the province to provide?

Indeed, a British Columbia Medical Association Policy Statement in June 2007 states "The BCMA advocates an abandonment of attempts to explicitly define the terms "medically necessary" or "medically required" as these relate to those services that are insured under the Medicare program".

However, by declaring certain cancer drugs and therapies to not be "medically necessary" the way is open

for those patients who have appropriate private insurance to obtain drugs and therapies on their own. Alberta, British Columbia, Manitoba, Ontario, Quebec (until *Chaoulli v. Quebec (AG)*, [2005] 1 S.C.R. 791) and PEI prohibit private insurance from covering “medically necessary” services. The other provinces do not.

Third, the absence of clear terminology in the *Canada Health Act* frustrates the requirements in section 23 of the *Act* that the provinces and territories report annually to Parliament on compliance with the *Act*. At a minimum, this reporting should include a requirement that the provinces identify, not only those services which are “medically necessary” on medical grounds, but also those services which are not “prescribed as medically necessary” on financial or other non-medical policy grounds. Disparities in funding among the provinces and territories would thus be highlighted.

The provinces and territories are limited in the amount of money and other resources which must be allocated among insured persons. Canadian courts have long recognized the ultimate authority of the provinces as funders to make decisions including the decision to not fund medical services or treatments even if the medical services or treatments are beneficial or in accordance with generally accepted medical practice.

But the last and most important problem is the failure of the Canadian health care system to honour the fundamental purpose which the *Canada Health Act* was intended to address, that no one should suffer catastrophic financial loss as a result of disease or disability. Where the health insurance plan of a province or territory fails to prescribe an otherwise medically valid service as “medically necessary” the province or territory may be in technical compliance with the *Canada Health Act*, but patients still suffer catastrophic loss.

Although the most pressing issue is to find better ways to more fairly allocate scarce resources so that catastrophic loss does not fall on particular patients, it is also essential to better define the terminology of the *Canada Health Act* and to expand the reporting requirements under section 23 of the *Act* so as to clearly define those circumstances where a provincial failure to fund a medically necessary service is made on economic grounds.

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## References

1. Flood, Colleen M: *The Anatomy of Medicare*. Canadian Health Law and Policy (2nd Edition, 2002) Chapter 1, pp. 22 and 21

The Romanow Commission on The Future of Health Care in Canada, an issue/survey paper entitled “Medically Necessary: What is it, and Who Decides?” (July 2002), considered whether the term “medically necessary” in the *Canada Health Act* should be defined. There have been numerous papers on the pros and cons of defining medically necessary services.

In a clinical sense, the words “medically necessary” or “medical necessity” could mean health care services provided to a patient for diagnosis or treatment of an illness, injury or disease by a physician or other health care provider based on reasoned clinical judgment. The services would reflect generally accepted standards or medical practice, and be based on credible scientific evidence, subject to peer review and generally acknowledged by reasonable medical practitioners. In this definition of “medically necessary” cost or cost-effectiveness is not a primary consideration.

See also the comment of Glen Griener “Defining Medically Necessity: Challenges and Implications” in *Health Law Review*, Volume 10, Number 3 at pages 6 to 8.

Health Canada’s definition of “medical necessity” is not definitive. There have been no judicial decisions defining the words “medical necessity” or “medically necessary” in the context of the *Canada Health Act*. There have been a number of judicial comments and decisions on these words in the context of provincial legislation. See, for example, *Cameron v. Nova Scotia* 177 D.L.R. (4th) 611.